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The Systematic Development of the Counselling for Alcohol Problems (CAP)

A Lay Counsellor Delivered Psychosocial Intervention for
Harmful Drinking in Primary Care

Abhijit Nadkarni

Thesis submitted in accordance with the requirements for the degree of
Doctor of Philosophy

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Department of Population Health

Faculty of Epidemiology and Population Health

London School of Hygiene & Tropical Medicine

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Research group affiliation(s): PREMIUM, Sangath, Goa, India

O thou invisible spirit of wine! If thou hast no name to be known by, let us call thee devil!

-William Shakespeare



Recovery needs support

Declaration

I, Abhijit Nadkarni, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

I have read and understood the School's definition of plagiarism and cheating given in the Research Degrees Handbook. I declare that this thesis is my own work, and that I have acknowledged all results and quotations from the published or unpublished work of other people.

I have read and understood the School's definition and policy on the use of third parties (either paid or unpaid) who have contributed to the preparation of this thesis by providing copy editing and, or, proof reading services. I declare that no changes to the intellectual content or substance of this thesis were made as a result of this advice, and that I have fully acknowledged all such contributions.

A handwritten signature in black ink, appearing to read 'Abhijit Nadkarni', with a stylized, cursive script.

Abhijit Nadkarni

1st December 2015

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Although only my name appears on the cover of this thesis, there are many people who have made this work possible and because of whom I will forever cherish the research experience described in this thesis. First and foremost, I would like to express my special appreciation and thanks to my supervisor and mentor Professor Vikram Patel, for encouraging me and for allowing me to grow as a researcher. His advice on this piece of research and on my career has been priceless. He sets very high standards and in trying to meet those, I believe, I have become a better researcher. He continues to remain an inspiration to make a difference to my chosen field of work through high quality research. A special thanks to my other mentor, Professor Richard Velleman, for constantly and gently shepherding me to complete my thesis on schedule. A friend, philosopher, and guide, Richard has not only supported me in the work described in my thesis but also helped me to think clearly about my future plans. I am deeply grateful to him for the long and thoughtful discussions that have helped me to think clearly about what I am doing and where I intend to go. I would like to thank my co-supervisor Dr Jim McCambridge whose insightful comments and constructive criticism helped me to focus my ideas. I would like to thank several people who have supported me in many ways at different stages of my research, without probably even realising the deep impact they made on my life. I would like to thank Prof Betty Kirkwood, Dr Mark Jordans, Prof Helen Weiss, Prof Pratima Murthy, Dr Mary De Silva, and Urvita Bhatia for their encouragement and support. This work could not have materialised without the involvement of many people from the PREMIUM project who worked on the frontlines and sometimes quietly behind the scenes. I would like to thank Dr Neerja Chowdhary, Arpita Anand, Dr Daisy Singla, Sachin Shinde, Dr Hamid Dabholkar, Dr Benedict

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Prologue

My thesis describes the systematic research process that led to a) the development of a contextually and culturally appropriate psychosocial intervention for harmful drinking, designed to be delivered by non-specialist health workers in primary care in India, and b) a framework to guide the development of contextually appropriate psychosocial interventions for low resource settings. My thesis is presented in the “Book Style” as described in the LSHTM Research Degree Handbook and the contents are presented with the aim of telling a coherent story about the development of a complex intervention in a low resource setting.

Keeping this in mind the thesis has been structured into eleven chapters. In Chapter 1, I describe the background and objectives of the intervention development process. In Chapters 2 to 10 I describe each step of the intervention development process; from identifying the evidence base, developing theory, and modelling processes to testing of feasibility and impact of the new intervention through case series and a pilot randomised controlled trial. In the last chapter of my thesis, I present a summary of my findings, implications of the findings, strengths and weaknesses, and an agenda for future work in the field of intervention development in low resource settings.

Due to the nature of the research being presented in the thesis every chapter does not follow the conventional structure of academic papers i.e. introduction, methods, results, and discussion. The chapters that describe each step of the intervention development process have conventional methods and results sections, which are bookended by a ‘background’ section which links the previous step (described in the chapter) to the current chapter, and an ‘output’ section which briefly describes the specific outcome of that particular step of the intervention development process. Finally, a footnote at the bottom of each chapter from Chapters 2 to 10 specifies my contribution to that particular step of the intervention development process, beyond writing this thesis.

Abstract

Harmful drinking adversely affects the drinkers' health, social, and occupational functioning, leads to immense societal costs, and causes a significant burden on global health. Despite this, policy makers, and consequently health systems, are disproportionately focused on providing care for dependent drinking, the more severe end of the alcohol use disorders spectrum. Consequently there is a large treatment gap for harmful drinking, especially in low- and middle-income countries where only a small proportion of those with harmful drinking receive appropriate psychosocial care. Two major barriers to providing care for harmful drinking are the shortage of adequately skilled specialist human resources and the lack of contextually appropriate psychosocial treatments suitable for low resource settings. The aim of my thesis is to describe the systematic process used to develop Counselling for Alcohol Problems (CAP), a brief psychosocial intervention for delivery by lay counsellors in routine primary care settings to men with harmful drinking in India. In my thesis I have described each step of the intervention development process which is broadly divided three sequential stages viz (i) identifying potential psychosocial intervention strategies; (ii) developing a theoretical framework for the new intervention; and (iii) evaluating the acceptability, feasibility, and preliminary impact of the new intervention. These three stages have nine steps that utilise a range of quantitative and qualitative participatory research methods to achieve the aims of the study. The outcome of the intervention development process is CAP a three-phase treatment delivered over one to four sessions based on a Motivational Interviewing stance and includes other strategies as follows: assessment and personalised feedback, family engagement, drink refusal skills, skills to address drinking urges, problem-solving skills and handling difficult emotions, and relapse prevention and management. To conclude, the outputs of the intervention development process were a) a contextually appropriate brief psychosocial intervention for harmful drinking designed to overcome specialist manpower shortages as it can be delivered by lay counsellors in primary care, and b) a structured framework to guide the development of contextually appropriate psychosocial interventions in low resource settings.

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Abbreviations

AA: Alcoholics Anonymous

ACI: Alcohol Consumption Index

AEFQ: Alcohol Effects Questionnaire

ALT: Alanine Aminotransferase

AR: Alcohol Reduction Instructions

ASI: Addiction Severity Index

AST: Aspartate Aminotransferase

ATM: Advisor-Teller-Money manager intervention

AUD: Alcohol Use Disorder

AUDIT: Alcohol Use Disorders Identification Test

BAC: Blood Alcohol Concentration

BASIS-32: Behaviour and Symptom Identification Scale

BC: Brief Counselling

BCT: Behavioural Couples Therapy

BI: Brief intervention

BMC: Brief Motivational Counselling

BMI: Brief Motivational Intervention

BST: Broad Spectrum Therapy

BT: Behavioural Therapy

CAP: Counselling for Alcohol Problems

CAU: Counselling as Usual

CBCST: Cognitive Behaviour Coping Skills Therapy

CBT: Cognitive Behaviour Therapy

CDT: Carbohydrate Deficient Transferrin

CHC: Community Health Centre

CM: Contingency Management

COMBINE: Combined Pharmacotherapies and Behavioural Interventions for Alcohol Dependence

CR: Counselling Relationship

CST: Communication Skills Training

CSV: Comma Separated Values

DALY: Disability Adjusted Life Years

DDP: Dynamic Deconstructive Psychotherapy

DDQ: Daily-Drinking Questionnaire

DMHP: District Mental Health Programme

DNRF: Drinking-Norms Rating Form

DRP: Dyadic Relapse Prevention

DSM IV: Diagnostic and Statistical Manual of Mental Disorders, 4th Edition

DWI: Driving While Impaired

ER: Emergency Room

EUC: Enhanced Usual Care

FGD: Focus Group Discussion

FO: Feedback Only

GCP: Good Clinical Practice

GFF: Group Face-to-Face Feedback

GGT: Gamma Glutamyl Transferase

GMET: Group Motivational Enhancement Therapy

GP: General Physician/Practitioner

GS: General Skills

GSC: Guided Self-Change

HCP: Health Care Provider

HIC: High Income Country

HO: Health Officer

IBT: Individual Based Therapy

IDC: Individual Drug Counselling

IDI: In Depth Interview

IFF: Individual Face-to-Face Feedback

INCAS: Indian Centre for Alcohol Studies

IRP: Individual Relapse Prevention

IRR: Incidence Rate Ratio

LMIC: Low and Middle Income Countries

LSHTM: London School of Hygiene and Tropical Medicine

MAC: Minimally Assessed Control

MALT: Munich Alcoholism Test

MAST: Michigan Alcoholism Screening Test

MATCH: Matching Alcohol Treatments to Client Heterogeneity

MBRP: Mindfulness Based Relapse Prevention

MCQ: Multiple Choice Questions

MCV: Mean Corpuscular Volume

MET: Motivational Enhancement Therapy

mhGAP: Mental Health Gap Action Programme

mhGAP IG: Mental Health Gap Action Programme Intervention Guide

MI: Motivational Interviewing

MITS: Motivational Interviewing Target Scheme

MM: Medications Management

MO: Medical Officer

MPHW: Multi-Purpose Health Workers

MRC: Medical Research Council

MSW: Medical Social Worker

MV: Missing Values

NCCDR: National Consultative Committee on De-addiction and Rehabilitation

NFHS: National Family Health Survey

NHS: National Household Survey

NHSDA: National Household Survey on Drug Abuse

NIMHANS: National Institute of Mental Health and Neuro-Sciences

NRT: Non Randomized Trial

NSHW: Non-Specialist Health Worker

NTX: Naltrexone

OCC: Optimized Community Care

OR: Odds Ratio

PAP: Primary Alcohol Problem

PGDCA: Post-Graduate Diploma in Computer Applications

PHC: Primary Health Centre

PHQ: Patient Health Questionnaire

PREMIUM: PRogrammE for Mental health Interventions in Under-resourced health systems

PT: Psychosocial Treatment

Q-CAP: Quality of Counselling for Alcohol Problems

QF: Quantity and Frequency

QFV: Quantity Frequency Variability

QRI: Quality of Recovery Index

RAPI: Rutgers Alcohol Problem Index

RCQ: Readiness to Change Questionnaire

RCT: Randomised Controlled Trial

REBT: Rational Emotive Behaviour Therapy

RMD: Rural Medical Dispensaries

SA: Simple Advice

SD: Standard Deviation

SF12: Short Form 12

SI: Strategy Increase Instruction

SIP: Shortened Inventory of Problems

SMD: Standardised Mean Difference

SO: Significant Other

STAR: Sangath Tool for Advanced Research

TAU: Treatment As Usual

TLFB: Time Line Follow Back

TM: Telephone Monitoring

TMC: Telephone Monitoring and Counselling

TSF: Twelve Step Facilitation

TSS: Treatment-Specific Skills

TTK: T.T. Ranganathan Clinical Research Foundation

UC: Usual Care

WHO: World Health Organization

YLD: Years Lost to Disability

YLL: Years of Life Lost

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Appendix 9: Role-plays for competency evaluation of lay counsellors

Appendix 10: Quality of CAP (Q-CAP)

Appendix 11: Timeline Follow Back (TLFB) (Only two months shown for illustrative purposes)

Appendix 12: Short Inventory of Problems (SIP-2R)

Appendix 13: PHQ-9 Screening Questionnaire

Appendix 14: Session evaluation for case series with lay counsellors

Appendix 15: End of treatment evaluation form for case series with lay counsellors.

Appendix 16: Question guide for IDI with patients who participated in the case series with lay counsellors.

Appendix 17: Question guide for FGD with lay counsellors who delivered CAP in the case series

Appendix 18: Question guide for IDI with counsellor supervisors

Appendix 19: Question guide for IDI with SOs of patients who participated in the case series

Appendix 20: Instructions to actor in the standardised role-play to test competency of lay counsellors at the end of the case series

Appendix 21: Counsellor instructions for the role-play

Appendix 22: Rating sheet for role-play

Appendix 23: Perceived global competency and attitude towards work of lay counsellors

Chapter 1 Introduction, Aims & Objectives

1.1 Global burden of alcohol use disorders

Alcohol Use Disorders (AUD) comprise a range of conditions related to excessive alcohol consumption and is recognised by the World Health Organization (WHO) as a distinct disorder; with hazardous drinking, harmful drinking and dependent drinking reflecting progressively more serious forms of the condition (Box 1.1) (Reid et al., 1999). AUDs are the third leading risk factor

Box 1.1: Alcohol Use Disorders (AUD) (WHO, 1993; WHO, 1994)

- **Hazardous drinking:** a pattern of alcohol consumption that increases the risk of harmful consequences for the user or others.
- **Harmful drinking:** a pattern of alcohol consumption that results in physical health, mental health, and social consequences for the user or others.
- **Dependent drinking:** is a cluster of behavioural, cognitive, and physiological phenomena that may develop after repeated and heavy alcohol use. These phenomena include a strong desire to consume alcohol, loss of control over its use, persistent drinking despite harmful consequences, a higher priority given to drinking than to other activities and obligations, tolerance, and withdrawal if alcohol use is discontinued.

for premature deaths and disabilities in the world accounting directly for 3.8% of global deaths and 4.6% of global disability-adjusted life years (DALY) (WHO, 2010a). A large proportion of this burden of disease is due to neuropsychiatric disorders, un-intentional injuries, liver cirrhosis, and cardiovascular diseases (Rehm et al., 2009). AUDs account for 9.6% (95% CI 7.7–11.8) of DALYs caused by all mental and substance use disorders, ahead of severe mental disorders like schizophrenia (7.4%; 95%

CI 5.0–9.8) and bipolar disorder (7.0%; 95% CI 4.4–10.3) (Whiteford et al., 2013). Furthermore, amongst all mental and substance use disorders, AUD are the largest contributor to premature mortality with 44.4% (95% CI 29.1–60.0) of Years of Life Lost (YLL) to mental and substance use disorder attributable to them (Whiteford et al., 2013). Finally, alcohol use is one of the five leading risk

factors for adult chronic disease, especially cardiovascular diseases and cancers (Lim et al., 2013). However, the large costs of AUDs to societies are not limited only to health-care costs, but also include unmeasured costs related to social harm, loss of productivity and direct law enforcement costs (Rehm et al., 2009).

1.2 Alcohol use in Low and Middle Income Countries (LMIC)

The burden of disease due to alcohol is closely related to the average volume of alcohol consumption; an association which is strongest in the poor and marginalized (Rehm et al., 2009) and hence has significant implications to LMIC). Consistent with this, alcohol was found to be the fifth highest risk factor for death in middle-income countries, highest risk for DALYs lost in middle income countries and eighth highest for DALYs lost in low income countries (Parry et al., 2011). Furthermore, in LMIC the prevalence of moderate to severe disability (31 million) and Years Lost to Disability (YLD) (18.4million) secondary to AUDs is more than four times that of high income countries (WHO, 2008). The public health impact of alcohol in LMICs is further highlighted by the finding that in 2010, alcohol use was the leading risk factor for disease and injuries in southern sub-Saharan Africa, largely increasing the risk of AUD (harmful drinking), road traffic accidents, other unintentional and intentional injuries, and tuberculosis (Lim et al., 2013). Similarly, alcohol use is an important risk factor for disease burden in South Asia and most of Latin America. In 2010, it was ranked second in central and tropical Latin America, and first in Andean Latin America as a risk factor for disease (Lim et al., 2013).

1.3 Alcohol production, marketing, regulation and policy implementation in LMIC

Globalisation has resulted in the ownership, promotion and marketing of alcohol in LMICs being increasingly controlled by multinational companies which in turn acts as a powerful driver of change in local customs and patterns of drinking in such developing societies (Jernigan, 2002).

Developing countries play an insignificant role in international trade of alcohol and the contribution of the alcohol industry to these economies is through a) adding to the gross national product through the service sector e.g. restaurants,

b) generating revenue for the state through excise, c) expenditure from the household budget, and d) generating employment in the alcohol industry (Jernigan, 2002). The growing interest of multinational alcohol companies in LMICs can be understood in the context of the hugely untapped markets in such countries. The beer market in China is worth about 12 billion USD a year and is expected to grow at the rate of five per cent every year and although the beer market in India is smaller than that of China, it is expanding faster (Andersson, 2008).

In response to this growing availability of alcohol in LMICs, various mechanism for regulating alcohol use and targeting the consumer, the conditions of sale, or the seller have been utilised in these countries, some of which have been successful, others not, as described below (Jernigan, 2002). State monopolisation of alcohol sales have been used in countries like Costa Rica and some places in India. This policy works through eradicating the profit-making motive, allows better control on numbers of sales outlets and on hours of sale. However such mechanisms are becoming

Box 2: Global alcohol production

- The top ten global spirits companies produce 58% of the cosmopolitan spirits, or about 25% of the total recorded spirits production.
- Eight of the top ten global spirits companies are headquartered in developed countries.
- The top ten beer producers, mostly headquartered in Europe or the U.S., contribute to 42% of the world production of beer.

(Jernigan, 2002)

increasingly rare because of the free-market ideology promoted by international financial agencies (Andersson, 2008). Countrywide or localised prohibition has been used in “fourth world” populations, some parts of India and in Islamic societies. Although prohibition initially results in improving social and health indicators, except for Islamic societies, it leads to the development of a vibrant black market for alcohol. Situational prohibitions on drinking, e.g. during football games in stadiums and their surroundings in São Paulo State in Brazil (Rehm et al., 2006) and during elections in India, are fairly widespread in developing countries. Age limits on drinking have been demonstrated to be effective in

reducing problems in the youth in developed countries but understandably if these regulations are not stringently implemented, as is usually the case in LMICs, they are bound to fail. Increasing alcohol taxation in developing countries only leads to increase in supply of illicit alcohol because of the relative inelasticity of demand for alcohol. Some developing countries have gone in the other direction and reduced taxation to make the destination more attractive for tourists and this has consequently led to worsened public health e.g. Mauritius (Rehm et al., 2006). Advertising and promotion restrictions are widely used but are effectively circumvented by the alcohol industry through non traditional advertising strategies like sponsorships (Andersson, 2008) e.g. Royal Challengers (Royal Challenge is a whisky in India) Bangalore cricket team owned by the United Breweries in India (Image 1.1).



Image 1.1: Surrogate marketing of alcohol in India

1.4 Alcohol use and India

India has historically been viewed as an abstinent culture (Bennett et al., 1993), a reputation that is ill deserved considering ancient practices (Murthy, 2015) and the contemporary epidemiological picture (Murthy et al., 2010). Historical documents have extensively recorded the production and use of various alcoholic beverages in ancient India, supported by archaeological evidence of alcohol distillation activities, described elaborate rules related to production and sale of alcohol, and the early recognition of the medical consequences of heavy alcohol use and interventions through disapprovals by the priestly and ruling elite (Benegal, 2005; Murthy, 2015).

In contemporary India, the consumption of alcohol varies greatly across the country with the prevalence ranging from 7% in the western state of Gujarat (despite official prohibition in the state) to 75% in the North-Eastern state of Arunachal Pradesh (Murthy et al., 2010). The National Household Survey of Drug Use, the first systematic effort to document the nation-wide prevalence of substance use in India showed that, after tobacco, alcohol (21.4%) was the most common substance of abuse (Murthy et al., 2010). Of those, 17-26% had alcohol dependence, translating to a population prevalence of about 4% (Murthy et al., 2010). Regional studies conducted over the years in India have revealed the prevalence of alcohol 'use/abuse' to range from 17 to 37% and the more severe AUD ('alcohol addiction' or 'alcoholism' or 'chronic alcoholism') to range from 0.2 to 3.4% (Murthy et al., 2010). The only incidence study on alcohol use from India found that annual incidence of nondependent alcohol use and dependent alcohol use among men was 0.3% and 0.2% respectively (Murthy et al., 2010).

Although there are relatively high abstention rates in contemporary India, as compared to Western countries, the rates of AUDs amongst those who do drink, are relatively high due to frequent and heavy drinking of spirits (Prasad, 2009). In fact, like the rest of the world, in India, AUDs are second only to depressive disorders as the leading neuropsychiatric cause of disease burden (WHO, 2008). In the post globalisation era, economic growth in India has fuelled the local alcohol industry, making India the target of market expansion by an ever-growing number of trans-national producers of alcoholic beverages (Prasad, 2009). This has resulted in an increase in alcohol availability, alcohol consumption and alcohol related problems. Furthermore, Indians are now beginning to drink at ever-younger ages (Pillai et al., 2014). In one part of India, the drinking population aged less than 21 years has increased from 2% to more than 14% in the past 15 years and the "average age of initiation" has dropped from 19 years to 13 years in the past two decades (Prasad, 2009). Finally, in India almost half of all drinkers drink hazardously and the signature pattern is one of heavy drinking, daily or almost daily drinking, under-socialized, solitary drinking of mainly spirits, drinking to intoxication and expectancies of drink-related dis-inhibition (Benegal, 2005). Hence the epidemiological picture of AUD in India is characterised by high rates of alcohol-attributable mortality and

prevalence of AUDs relative to the per capita volume of alcohol consumed (Rehm et al., 2009). Table 1.1 summarises the epidemiological picture of alcohol use and AUDs in India.

Data about alcohol use and AUD in women is relatively poorly documented in India. From the limited evidence that is available it is clear that prevalence of drinking and AUD is significantly lower in women than in men in India. In a national survey 1% women reported regular use of alcohol (Neufeld et al., 2005). A study from an urban centre in South India reported that women who do drink, have patterns of equally heavy alcohol use as men (Benegal et al., 2003). In that study the average consumption on typical drinking occasions, in both men and women, was five standard drinks. In another study from South India, 6 % of female participants reported drinking alcohol at least once in the last 12 months, 84% were lifetime abstainers and 10% women were current abstainers with a history of alcohol use (at least once) in their lifetime (Benegal et al., 2005). Two per cent of the female participants were frequent (weekly or more) heavy (5+ drinks) drinkers, translating into 28% of female drinkers (Benegal et al., 2005). Although women drank significantly less often than men, and drank significantly less drinks per year, 28% of women drinkers were hazardous drinkers (Benegal et al., 2005).

Table 1.1: Prevalence of drinking and alcohol use disorders in India (Adapted) (Gururaj, 2011; Murthy et al., 2010)

Author, Year	Setting, State	N	Focus of enquiry	Prevalence
Benegal, 2008	Island population, Andaman and Nicobar	18,018	Alcohol use	34.7% (men), 6.3% (women)
Chavan, 2007	Rural, Slum, Punjab	59,470	Alcohol dependence	12%
Gururaj, 2006	Urban, Rural, Semi-rural, Slum, Karnataka	28,507	Alcohol use	32%
National Family Health Survey (NFHS-3) (Murthy, 2010)	Urban, Rural, Semi-rural, Slum	198,754	Alcohol use	1/3 of men and 2% women
Gururaj, 2004)	Urban, Rural, Semi-rural, Slum, Karnataka	10,168	Alcohol use	9%
National Household Survey on Drug Abuse (NHSDA)(Ray, 2004)	Urban, Rural, Semi-rural, Slum	40,697	Alcohol use	21.4% of men
Benegal, 2003)	Urban, Rural, Karnataka	21,276	Alcohol use	15.3%

Author, Year	Setting, State	N	Focus of enquiry	Prevalence
Gupta, 2003	Urban, Maharashtra	50,220	Alcohol use	18.8%
Meena, 2002	Urban, Haryana	142,000	Alcohol use	19.8%
Mohan, 2002	Urban, Delhi	10,312	Alcohol use	5.9%
Sharma, 2001	Urban, Goa	4,022	Alcohol dependence	0.1%
National Household Survey (NHS), 2000-01(Murthy, 2010)	Urban, Rural, Semi-rural, Slum	40,697	Alcohol use	21.4%
Hazarika, 2000	Rural, Assam	312	Alcohol use	37%
National Family Health Survey (NFHS-2), 1998-99 (Murthy, 2010)	Urban, Rural, Semi-rural, Slum	486,011	Alcohol use	17% (men), 2% (women)
Singh, 1998	Urban, Uttar Pradesh	1806	Alcohol use	10.4%
Ghulam, 1996	Urban, Madhya Pradesh	5236	Alcohol use	37.6%
Zulfikarali, 1994	Urban	254	Alcohol use	16.7%

Author, Year	Setting, State	N	Focus of enquiry	Prevalence
Premranjan, 1993	Urban, Pondicherry	115	Alcohol dependence	3.5%
Ponnudurai, 1991	Urban, Tamil Nadu	2334	Alcohol abuse	16.7%
Varma, 1980	Urban, Rural, Punjab	1031	Alcohol use	23.7%
Sethi, 1979	Rural, Uttar Pradesh	2415	Alcohol abuse	43.5%
Lal, 1979	Urban, Punjab	6699	Alcohol use	29.3%
Thacore, 1972	Urban, Rural, Uttar Pradesh	2696	Habitual excessive alcohol use	49%
Varghese, 1973	Urban, Tamil Nadu	2904	Chronic alcoholism	0.5%
Gopinath, 1968	Rural, Karnataka	423	Alcoholism	0.2%

1.5 The business aspects of alcohol use

The Indian Made Foreign Liquor (IMFL) market (175–200 million cases annually) in India is increasing annually at 10 to 15% and the sale of Indian whiskies grew by 65-70% in the past decade (Gururaj, 2011; IWSR, 2010; Kurien, 2006). A recent sub-trend has been the increased consumption of white spirits (an annual compounded growth rate of 35-40%) with 50% of vodka drinkers being first-time drinkers (IWSR, 2010). There has also been an increase in the consumption of beer in India with four South Indian States accounting for about 45% of beer consumption (Gururaj, 2011). Wine is mainly consumed in urban India with the two metros of Mumbai and Delhi accounting for approximately half the country's wine sales (Gururaj, 2011). Although country liquor (indigenous low-quality alcoholic drink popular in the urban poor and rural India; and made from a range of fermented high sugar content fruits) was initially systematically marketed to counter the hazards of cheap illicit liquor, the increasing excise duty rates on the former over the years has led to there being no difference in prices between the two types of liquor and consequently the illicit alcohol trade continues to flourish (Sinha, 2005).

India has one of the largest alcohol beverage industries in the world. India produces 65% of the alcohol manufactured in South Asia [1.3 billion of the 1.7 billion population of South Asia lives in India] (<http://data.worldbank.org/?locations=8S-IN>) and contributes to about 7% of total alcohol beverage imports into the South East Asian region (behind Thailand, Myanmar, and Sri Lanka) (Gururaj, 2011). Between 1982 and 1992, the production of absolute alcohol in India increased approximately by 250%. There are about 310 working distilleries throughout the country and at last count there were more than 2,800 wholesale and 67,000 retail alcohol outlets in India (Sinha, 2005).

In 2004, the legal Indian alcohol beverage industry was valued at 600 billion rupees (approximately 10 billion US Dollars) (Deccan Herald, 2004). Although precise data is not available it is estimated that the spirits industry employs about 50,000 people directly and 250,000 indirectly (Gururaj, 2011). Furthermore, it is estimated that for every job in the brewing sector, one job is generated in the retail, two in the supply sector and 12 in the hospitality industry (ICAP, 2006). Taxes on alcoholic beverages constitute the second largest

revenue-earner for most state governments and constitute 90% of the state excise duties (Abraham, 1995; Sengupta, 2005). Taxes on alcohol beverages contributed to an estimated 216 billion rupees (approximately 3.2 billion US Dollars) in the year 2003-04 and leading liquor-consuming states collect between 25 billion and 40 billion rupees (approximately 37-60 million US Dollars) annually from liquor companies in the form of taxes (Damodar, 2004). The bigger states earn 15-19% of their total tax revenues from excise taxation on alcohol and nearly a third of the Indian states earn more than 15% of their total revenues from alcohol. Furthermore, several states are witnessing continued increases in revenue collections from this source (Gururaj, 2011).

It is evident that there is a continued and greater reliance of the Indian states on alcohol revenues. In fact these revenues now almost match the budgetary outlay and expenditure related to medical and public health, family welfare and water supply and sanitation. For the year 2008-09, state excise duties put together was 392 billion rupees (approximately 5.9 billion US Dollars) while the expenditure on health and related budgets was 439 billion rupees (approximately 6.6 billion US Dollars) (Gururaj, 2011). On the other hand, the amount of the budget spent on the management of alcohol related problems remains a very small proportion of total state health expenditure. It is important to note that good quality of data on these issues is lacking in India and there is a real possibility that the figures quoted above are an under-estimate.

How does this compare with Europe? According to Cnossen (2007), excise duty collections on alcohol range from 0.2% of the total tax revenue in Italy to 2.5% in Poland and Ireland. Except for a few countries, such as UK and Ireland, alcohol excise duties do not generate significant revenue for the EU member states. In absolute numbers, alcohol duty collections per adult range from €19 (Italy) to €318 (Ireland) or €2 per liter of pure alcohol (Finland) to €33 per liter (Portugal). Furthermore, alcohol excise collections are significantly high in northern EU, but negligible in southern EU. On the other hand, the direct external costs of alcohol use such as health care, crime, and traffic accidents are remarkably similar across EU states (approximately 0.7% of the GDP). Except in Finland, in all the other EU states the costs per adult and per liter of pure alcohol exceed the excise collections and the effective duty rate,

respectively, by a wide margin. This is despite the fact that these external costs are an underestimate as they do not include the value of the life of non-drinkers lost in alcohol-related crime and traffic accidents, social benefit payments, and loss of productivity due to absenteeism, unemployment and premature mortality (Cnossen, 2007).

1.6 Alcohol use in the study setting

1.6.1 The context

My thesis is based on a study primarily conducted in the state of Goa, in western India (Image 1.2). According to the 2011 census, the population of India is 1.2 billion (Government of India, 2011); and Goa is one of its smallest



Image 1.2: Goa on the Indian map

states. The population of Goa is just over 1.4 million people, of which 62% live in urban areas (Government of India, 2011). It has been reported that there is a strong relation between economic wealth and alcohol consumption in low-income countries; the higher the gross domestic product, greater the overall volume of consumption and lower the proportions of abstainers (Rehm et al., 2009). This is particularly relevant to Goa as it ranks fourth in the National Human Development Index with one of the

lowest poverty indicators in the country (Gandhi et al., 2011). Furthermore, alcoholic drinks are easily available here at cheaper rates than neighbouring states, due to lower excise duties (Patel et al., 2001) and local production of alcohol from the cashew fruit (Image 1.3 and Image 1.4). Hence, unlike most of India, Goa has a more liberal, 'wet' culture towards drinking and this is reflected in lower abstinence rates.

The epidemiological picture of drinking and AUD in Goa is described in the following section and summarised in Table 1.2.

1.6.2 Alcohol use in Goa

The prevalence of current drinking and AUD varied depending on the setting of the study. The prevalence of current drinking (past one year) in a community sample of men was 39 % (95 % CI 36–42) (Pillai et al., 2013). In primary care the prevalence of drinking in men was 59% (D'Costa et al., 2007) and amongst male industrial workers the prevalence of drinking was 69% (Silva et al., 2003).



Image 1.3: Cashew fruit



Image 1.4: A traditional Cashew Feni distillation unit

1.6.3 Alcohol use disorders in Goa

In a community sample of men, 15% of current drinkers drank at a high- risk level. More specifically, 29% drinkers reported monthly or more frequent heavy episodic drinking and 34% drinkers reported monthly or more frequent drunkenness (Pillai et al., 2013). In primary care settings the prevalence of hazardous/harmful/dependent drinking (AUDIT score >7) was 8.2% (95% CI 2.8-21.5): 15% (95% CI 5.7-33.7) in men and 0.7% (95% CI 0.15-2.9%) in women (D'Costa et al., 2007). Of the men who scored >7 on the AUDIT, 54% were hazardous drinkers (AUDIT score 8-15), 16% were harmful drinkers (AUDIT score 16–19) and 30% were dependent drinkers (AUDIT score of 20 or more). In a study of male industrial workers in Goa, the prevalence of hazardous/harmful/dependent drinking (AUDIT score >7) was 21% in the full sample and amongst drinkers it was 31% (Gaunekar et al., 2005; Silva et al., 2003).

1.6.4 Drinking patterns and correlates of AUD in Goa

Image 1.5: A 'wine shop' in Goa



drinkers preferred spirits and drinking in bars while casual drinkers preferred beer and the drinking was done at home or at social gatherings. They indulged in binge drinking and early morning drinking, had lesser number of days of abstinence in the previous year and made fewer attempts to abstain from alcohol. Although they were aware they had a drinking problem only 6%

Risky drinking patterns were associated with lower education, lower socio-economic status, older age, being separated, rural residence, common mental disorders, sexual risk behaviours, intimate partner violence, acute alcohol-related consequences, and alcohol dependence (Pillai et al., 2013). Hazardous



Image 1.6: Bottles of Cashew and Coconut Feni for sale in a 'wine shop' in Goa

had sought help for their drinking, most often from friends/family or the company doctor. Compared to abstainers, hazardous drinking industrial workers were significantly more likely to have taken a greater number of days of sick leave, to be smoking cigarettes, to have higher disability scores and poorer mental health (Gaunekar et al., 2005). Hazardous drinkers reported more injuries in the form of fractures and head injuries, were at higher risk of being hospitalised and were spending more money on health care (Silva et al., 2003). Finally, hazardous drinkers were more likely to be Catholic, middle-aged, users of tobacco, and illiterate; and reported more psychological symptoms (D'Costa et al., 2007).

1.6.5 Contextualising drinking in Goa and India

Lifetime alcohol abstinence rate in India (79.2 %) is higher than the average abstinence in African (57.3 %), American (21.5 %), and European (18.9 %) regions (WHO, 2011), but the rates of AUD amongst drinkers are higher than in developed countries (Ray, 2004). The prevalence of drinking and AUD among men in Goa is lower compared with that in many western countries (WHO, 2011) but is higher than many parts of India (D'Costa 2007, Murthy, 2010; Pillai, 2013; Silva, 2003). Finally, the adverse impacts of AUD in Goa are similar to those reported in the rest of the world (Caetano, 2000; D'Costa, 2007; Gaunekar, 2005; Hatton, 2009; Lipsky, 2011; Pillai, 2013; Silva, 2003; Volk, 1997).

Table 1.2: Summary of epidemiological research on alcohol use and AUD in Goa

Author, Year	Setting	Sample	n	Summary findings
Pillai, 2013	Community	Males, 18-49 years	1899	<ul style="list-style-type: none"> • 14.8 % current drinkers drank at a high- risk level. • 28.6 % drinkers had monthly or more frequent heavy episodic drinking. • 33.7 % drinkers had monthly or more frequent drunkenness, respectively. • Risky drinking patterns were associated with the following: lower education, lower socioeconomic status, older age, being separated, rural residence, common mental disorders, sexual risk behaviours, intimate partner violence, acute alcohol-related consequences, and alcohol dependence.
D'Costa, 2007	Primary care	Males	826	<ul style="list-style-type: none"> • 15% men were hazardous drinkers. • Hazardous drinkers were more likely to be illiterate, have a psychological disorder, use tobacco, become victims of crime, and be perpetrators of interpersonal violence.
Gaunekar, 2005	Community	Male industrial workers	234	<ul style="list-style-type: none"> • Hazardous drinkers preferred spirits and drinking in bars. • Binge drinking and early morning drinking were common in hazardous drinkers. • Only 6% hazardous drinkers had sought help for their drinking

Author, Year	Setting	Sample	n	Summary findings
				<ul style="list-style-type: none"> Hazardous drinkers were significantly more likely to have taken a greater number of days of sick leave, be smoking cigarettes, have higher disability scores, and have poorer mental health
Silva, 2003	Community	Male industrial workers	984	<ul style="list-style-type: none"> Prevalence of hazardous drinking was 21%. Hazardous drinking was associated with common mental disorders, head injuries, and hospitalisations.

1.7 Health policy response

Such an epidemiological picture, as prevalent in India, calls for a decisive national alcohol policy tackling the problem at various levels, from prevention to treatment and care, which has unfortunately been lacking. Some of the challenges to the development and implementation of an effective national alcohol policy in India are conflicts between the Central Government and the State Governments on issues related to the production, distribution, taxation and sale of alcohol, a greater emphasis on the alcohol industry as a source of revenue generation, an increasing emphasis on illicit drugs compared to alcohol, absence of inter-sectoral (e.g. health, law, revenue) coordination on this issue, and the limited high quality population-based national level data on alcohol use (Johnson, 2013). Amongst all these, the biggest barrier is the harsh reality that the government derives a substantial proportion of its revenue from alcohol taxation and is highly influenced by a powerful alcohol industry lobby. This underscores the basic conflict of interest for the State, which on the one hand generates substantial income from the alcohol industry, and on the other hand also has responsibility for the health of the people.

However, although India does not have a consolidated national alcohol policy, in recent years there have been some attempts at dealing with the public health problem of AUD through a range of disconnected policy initiatives as described below (Johnson, 2013). In 2001, the Ministry of Food Processing Industries, the Central Government's nodal agency on alcohol policy, set up a "Joint Working Group on Rationalization of Excise Policy and Taxation" which came out with a draft "Model Excise Policy and Excise Act" to be adopted and implemented in all the States and Union Territories in India. However, the Government of India is yet to take a final decision with regard to this Act. Similarly, another draft policy that awaits final approval of the Government of India is the National Policy on Substance Use (2012) that was prepared by the National Consultative Committee on De-addiction and Rehabilitation (NCCDR) set up in 2009 by the Ministry of Social Justice and Empowerment, the Central Government's nodal agency on demand reduction. After India adopted the 'WHO Global Alcohol Strategy to Reduce the Harmful Use of Alcohol' the Ministry of Social Justice & Empowerment, Government of India organised a national workshop on 'Developing a National Strategy to Reduce the Harmful Use of Alcohol in tune with the WHO Global Strategy' in 2010, and regional Workshops on 'Evolving

Effective Strategies for Alcohol Advocacy & Prevention'; and a national resource called the Indian Centre for Alcohol Studies (INCAS) committed to alcohol policy advocacy was also established in 2012. Finally, an Advisory Group Meeting organized by WHO-India jointly with the Ministry of Health & Family Welfare, Government of India in 2013, recognized alcohol as major agenda item in the National Framework for Monitoring the Prevention and Control of NCD and also approved a specific target of 10% relative reduction in 'alcohol use'.

Despite all these initiatives, any official response to the growing public health problem of AUD remains focused predominantly on the visible tip of the iceberg i.e. alcohol dependence. Although alcohol dependence is the most severe form of AUD, it affects only around 4% of the adult male population while the bigger public health problem is the more than 20% of the adult population that has hazardous drinking (Prasad, 2009). This lop-sided policy focus on tertiary prevention has led to the Government of India funding 483 detoxification and 90 'counselling' centres across the country through the National Drug De-addiction Programme (Prasad, 2009). However, many of these centres are defunct and the existing centres are not adequate to meet the requirements as they are plagued by problems like lack of adequately trained staff and limited accessibility. A testimonial to the limited reach of the current approach is the paradoxical observation that the rates of help-seeking in these centres are the lowest in states with the highest prevalence of alcohol use (Ray, 2004). This effectively means that a large proportion of people with AUD in India do not have access to help for their alcohol related problems.

1.8 Approaches to prevention and treatment of AUD

There is growing evidence of the effectiveness of programmes aimed at individuals, community based approaches and national policies targeted at prevention and reduction of alcohol-related problems (Norstrom, 2003; Wagenaar, 2002). Most of the robust evidence comes from developed countries (Nordic Council for Alcohol and Drug Research, 2002), with limited information based on case studies from developing countries (Room, 2002). However, there is no reason to believe that the general principles based on this evidence would not be applicable in developing countries, provided the implementation is adapted to the unique requirements of that particular culture. In the next

section, I will summarise the evidence base of interventions for prevention and treatment of drinking problems.

Although school based education and public information campaigns are popular and widely used strategies aimed at prevention of alcohol problems the evidence for their effectiveness is largely discouraging. The large body of work assessing increasingly sophisticated school based alcohol education programmes (Paglia, 1999) demonstrates that although such programmes increase knowledge and change expressed attitudes, they do not have much effect on actual drinking behaviour (Babor, 2003); and even if changes occur they are not lasting (Foxcroft, 2003). Similarly the experiences with public information campaigns too have not been very encouraging (Babor, 2003).

There is strong evidence which demonstrates that alcohol consumption is responsive to price. Furthermore, heavy drinkers, like other drinkers, are affected by prices of alcohol (Kuo, 2003; Vuchinich, 1999) and consequently increased taxation on alcohol reduces mortality rates due to liver cirrhosis and drink-driving, as well as rate of violent crime (Chaloupka, 2002; Cook, 1993; Cook, 1981). More specifically, evidence from the UK shows that a 10% rise in alcohol prices would reduce alcohol related deaths in men by 29% (Norstrom, 2002). Besides increasing price, reduction in the availability of alcohol too reduces amount of drinking and alcohol-related problems. There is good evidence to show that restriction of the hours and days of alcohol sale and the numbers and types of alcohol outlets, and raising of drinking age are effective measures to reduce alcohol consumption (Babor, 2003; Chikritzhs, 2002; Gruenewald, 1993; Makela, 2002; Norstrom, 2003; Ragnarsdottir, 2002; Wagenaar, 2002).

Just as preventives measures are focused on reducing drinking, preventive strategies can also be focused on the adverse impacts of drinking. One such set of measures is drink-driving countermeasures that have strong evidence of effectiveness in reducing alcohol-related traffic injury. These countermeasures include laws forbidding driving above a stated blood-alcohol concentration, sustained police attention to drink driving, sustained programme of publicised and random breath-testing, and graduated licensing measures (Babor, 2010; Henstridge, 1997; Shults, 2001). Preventive measures can also be focused on

reducing violence and casualties around public drinking. Server training and enforcement of policies denying alcohol service to those who are already intoxicated or underage lead to lower rates of customer intoxication, reduced drink-driving casualties and violence (Holder, 2004; McKnight, 1991; Wallin, 2003). Obviously, such strategies are focused on drinking in public places, and hence are relevant only to cultures with strong traditions of pub or restaurant drinking.

Finally, a range of interventions is available for the treatment of alcohol related problems. They are broadly summarized as follows. 'Brief interventions' are evidence based, short, focused psychosocial interventions that are designed to be delivered by non-specialists before or soon after the onset of alcohol related problems and are typically designed to reduce the heavy drinking in high-risk drinkers (Bien, 1993; Kahan, 1995; Poikolainen, 1999; Wilk, 1997). More severe alcohol problems require specialised treatments required to manage alcohol withdrawal, prevention of relapse and rehabilitation. These include medically assisted detoxification using benzodiazepines in inpatient and outpatient settings (Naranjo, 1986), residential or outpatient rehabilitation programmes (Finney, 1996; Longabaugh, 1983; Miller, 1986), psychosocial interventions (e.g. behaviour therapy, motivational enhancement therapy, Twelve Step Facilitation, family therapy) (Ouimette, 1999; Project MATCH Research Group, 1998; Project MATCH Research Group, 1997), and pharmacotherapy (e.g. Naltrexone, Acamprosate, Disulfiram) (Garbutt, 1999; Kranzler, 2001; Kranzler, 2000; Swift, 1999).

Although there is sufficient evidence for a range of effective preventive and treatment strategies for AUD, most of the evidence comes from developed countries. Hence, while extrapolating the principles of these strategies to LMIC settings it is necessary to take into consideration the resource availability and ground realities related to local policy making. While acknowledging the importance of policy level strategies like increased taxation my thesis focuses on one end of the stepped-care framework i.e. identification and treatment of alcohol-related problems in primary health care. The subsequent sections of this chapter focus on the 'treatment gap' for people who have already developed AUD and the proposed solutions to reduce this 'treatment gap' in low resource settings.

1.9 The ‘Treatment Gap’

The ‘treatment gap’ has been defined as the proportion of people with an illness, disease, or disorder who need treatment but do not get it (Kale, 2002). The ‘treatment gap’ for people with mental disorders has been extensively documented. More than half the persons with mental disorders do not receive cost-effective interventions in most parts of the world; the treatment gaps are higher in LMIC where they approach levels of 90% (Wang et al., 2007). Among all mental disorders, globally, AUD have the widest treatment gap; the contact coverage of care for AUD is less than 20% in most countries (Kohn et al., 2004). Furthermore, as most patients who are in contact with services do not have their AUD recognized or receive evidence-based interventions, the ‘effective’ coverage gap is likely to be even larger (De Silva et al., 2014).

Although medications form one component of treatment for some types of AUD, successful long-term recovery is dependent on psychosocial interventions that focus on building motivation to change, and support changing of maladaptive behaviours and expectations about alcohol. However, the vast majority of people with AUD who live in LMIC do not have access to any structured psychosocial interventions. In LMIC, two major barriers to making psychosocial interventions accessible are the lack and inequitable distribution of skilled human resources for delivering such interventions and concerns regarding the contextual appropriateness and generalisability of interventions developed in ‘western’ cultural settings (Knapp et al., 2006; WHO, 2005a).

1.10 Bridging the ‘Treatment Gap’

One disruptive innovation to overcome the barrier posed by the lack of specialist human resources to deliver psychosocial interventions is through task sharing i.e. rational redistribution of tasks among health workforce teams. Non-specialist health workers (NSHW) are one such human resource with which health care tasks can be shared. NSHWs are first-level providers who have received general rather than specialist mental health training and include professionals (doctors, nurses and other general paraprofessionals) as well as non-professionals (such as lay providers) (van Ginneken et al., 2013). NSHWs are also conceptualised based on their background and level of training as lying

on a spectrum with the 'natural helper' (unpaid community members) at one end and the 'para-professional' (paid workers with minimal qualifications, trained and demonstrating acceptable levels of standardised competencies) at the other (Eng et al., 1997). Use of NSHWs in frontline healthcare delivery is not a novel concept in other areas of global health, and such use of NSHWs has shown generally encouraging results. In the fields of maternal and child health, as well as in communicable diseases, the use of Community Health Workers has demonstrated effectiveness in increasing access to care e.g. promoting immunisation uptake and breastfeeding, improving TB treatment outcomes, and reducing child morbidity and mortality (Lewin et al., 2010; Swider, 2002; Viswanathan et al., 2010).

The role of NSHWs in healthcare delivery has a roller coaster history. The WHO's Alma-Ata Declaration in 1978 (WHO, 2005b) re-defined public health in the twentieth century by identifying the primary care system as the fulcrum around which a national health system should develop. This spurred the development and rapid expansion of NSHW driven programmes in LMICs but in the following decade the cost effectiveness of such programmes was increasingly questioned (Franke, 1992; Walt, 1990). The 90s saw increasing health inequalities within and between countries, resurgence of several infectious diseases and the spread of the AIDS epidemic, as well as the inability of the existing public health systems to deal with increasing chronic non communicable diseases and that led to a renewed interest in NSHW programmes, especially in LMICs (Hadley and Maher, 2000; Lehmann et al., 2009; Maher et al., 1999). At that time, in developed countries NSHWs were primarily seen as a mechanism to deliver health care to minority communities poorly accessible to conventional healthcare systems (Witmer et al., 1995). In the new millennium the interest in NSHWs was renewed because of the growing concern regarding the specialist human resource crisis in health care in many LMICs (WHO, 2005a). Thus, over time, a good body of evidence has developed demonstrating the benefits of NSHWs in healthcare.

Interventions designed to be delivered by NSHWs are an important strategy in reducing the treatment gap for mental health problems in the absence of

specialist human resources, especially in LMICs. The estimated total number of mental health care workers needed in LMICs in 2005 was 362, 000 (22.3 per 100,000 population in low-income countries and 26.7 per 100,000 in middle-income countries), an overall shortage of 239,052 mental health workers (17.3 per 100,000 population in low-income countries and 14.9 per 100,000 population in middle-income countries) (Kakuma et al., 2011). Extrapolated to all 144 LMICs there was a shortage of 1.2 million mental health workers and all low-income countries and about two thirds of middle-income countries had a shortage of health workers to deliver a core set of mental health interventions (Kakuma et al., 2011). Task sharing is one way of overcoming this human resource barrier and NSHWs trained and supervised by specialists have been able to effectively detect and treat mental disorders, refer appropriately, and provide psycho-education and follow-up care; and worked in a range of settings like clinics, halfway homes, and community outreach services, providing services for common mental disorders, severe mental disorders, epilepsy, learning disabilities, and dementia using complex stepped-care interventions, group interpersonal therapy, cognitive behavioural therapy, and psycho-educational programmes for caregivers (Araya et al., 2003; Bolton et al., 2003; Chatterjee et al., 2009; Dias et al., 2008; Patel et al., 2010; Rahman et al., 2008; Ran et al., 2003; Rojas et al., 2007; Xiang et al., 1994).

A recent meta-analysis shows that compared to usual healthcare services, NSHWs may increase recovery from depression and/or anxiety, reduce symptoms in mothers with perinatal depression, reduce the symptoms of PTSD, improve the behavioural symptoms of people with dementia, improve mental well-being, burden and distress of carers of people with dementia, and decrease the amount of alcohol consumed by people with alcohol-use disorders (van Ginneken et al., 2013). However, when it comes to AUD, there are, at present only two published randomised controlled trials (RCT) of a NSHW delivered intervention for any form of AUD from a LMIC (Noknoy et al., 2010; Papas et al., 2011) (Table 1.3). In the primary care based study from Thailand, Motivational Enhancement Therapy (MET) delivered by nurses to hazardous drinkers was significantly superior to 'assessment only' in reducing a range of risky drinking outcomes (Noknoy et al., 2010). In a HIV clinic

based study from Kenya, Cognitive Behaviour Therapy (CBT) delivered by lay counsellors to hazardous or binge drinkers was superior to usual care and demonstrated large effect sizes (Papas et al., 2011).

Table 1.3: RCTs of NSHW delivered intervention for AUD in LMIC

Author, Year	Country	Setting	Delivery agent	Type of AUD	n	Intervention	Control	Results
Noknoy, 2010	Thailand	Primary care	Nurse	Hazardous drinking	117	Motivational Enhancement Therapy (MET)	Assessment only	Drinks per drinking day, frequency of hazardous drinking, and of binge drinking sessions were reduced in the intervention group more than in the control group ($p < 0.05$) after both 3 and 6 months
Papas, 2011	Kenya	HIV clinic	Lay counsellors	Hazardous or binge drinking	75	Cognitive Behaviour Therapy (CBT)	Usual care	Large effect sizes (Cohens d) at 30 day follow up: Per cent drinking days 0.95 and Drinks per drinking day 0.76

A few years ago, the Grand Challenges in Global Mental Health initiative identified research priorities that will make a substantial and immediate impact on the lives of people with mental health problems (Collins et al., 2011). Almost all of the leading priorities identified by this initiative were related to expanding access to evidence based interventions for mental health problems (Collins et al., 2011). It could be achieved through various ways and include designing a methodology for the development and evaluation of psychosocial interventions delivered by NSHWs, integrating packages of care into routine primary health care, and providing effective and affordable community-based care and rehabilitation.

However, in trying to increase access to interventions for AUD it is important to remember that contextual differences play an important role in the development and treatment of substance use disorders as culture has a significant influence on differences in substance use histories, types of substances used, health consequences of substances used, attitudes towards substance use and treatment, pathways to treatment (and their interactions with issues like spirituality), and patterns of treatment engagement and retention (Buser, 2009; Campbell et al., 2006; Epstein et al., 2000; Hahm et al., 2003; Iguchi et al., 2005; Jackson-Gilfort et al., 2001; Klonoff and Landrine, 2000; Moselhy and Telfer, 2002; Shillington and Clapp, 2003; Strada and Donohue, 2006). An example of the differential effect of interventions for substance use disorders depending on culture is the Real Men Are Safe programme, an HIV risk-reduction intervention for substance abusing men, which was less effective with Black than White male substance users and several other studies in which interventions with limited effectiveness in White substance users were more beneficial for ethnic minorities (Burlew et al., 2011; Calsyn et al., 2013; Covey et al., 2010; Montgomery et al., 2011; Winhusen et al., 2008). Hence along with developing psychosocial interventions that can be delivered by NSHWs, it is also important to develop interventions that are responsive to the context in which they will be delivered.

However, although there are supporters of contextual adaptations of psychosocial interventions, the questions around effectiveness of contextually adapted psychosocial interventions are not fully answered. The evidence from two large meta-analyses is mixed regarding the effectiveness of such adapted

interventions (Huey Jr and Polo, 2008; Smith and Griner, 2006). Although there is some evidence about the effectiveness of adapted interventions, they are not always as effective as the original intervention. However the adaptations generally demonstrate a greater fit to the needs of a targeted cultural group. An important factor that contributes to psychosocial interventions developed in western cultural contexts retaining their effectiveness in different cultural contexts, is the systematic methodology followed to make the adaptations. In a recent meta-analysis co-authored by the author of this thesis we found that in interventions for depressive disorders adapted using systematic methodology there was a statistically significant benefit in favour of the culturally adapted interventions (standardized mean difference -0.72 , 95% confidence interval -0.94 to -0.49) (Chowdhary et al., 2014).

1.11 Aims and objectives

To summarise, despite the significant burden of AUD in LMICs there is a large treatment gap and one of the ways of reducing the treatment gap is by developing contextually appropriate interventions that can be delivered by NSHWs based in primary care. The purpose of my thesis is to describe the systematic development of a brief psychosocial intervention for harmful drinking to be delivered by lay counsellors in routine primary care settings. The intervention was developed to address harmful drinking in men only, because the vast majority of persons with any kind of AUD in India are men (Murthy et al., 2010).

The work described here is a part of the PRogrammE for Mental health Interventions in Under-resourced health systeMs (PREMIUM) project whose goal was to develop psychosocial interventions for harmful drinking and depressive disorders based on both global and contextually relevant evidence and with emphasis on both acceptability to patients and feasibility for delivery by lay counsellors in routine health care settings (Nadkarni et al., 2015). The aims of this thesis and the methods used to achieve these aims are described in Table 1.4 and graphically represented in Figure 1.2.

Table 1.4: The aims and corresponding methods of this thesis

Aim of formative research	Method
Understanding the available evidence and identifying gaps those need to be addressed during intervention development.	<ul style="list-style-type: none"> • Identifying an appropriate, high quality, recent systematic review. • Updating the recent review.
Proposing a theory on how the intervention will potentially work.	<ul style="list-style-type: none"> • Identifying existing evidence on explanatory models of AUD through review of the literature. • Qualitative research involving experts in the field, intended recipients of the intervention and potential delivery agents. • Identifying suitable intervention components through a survey of experts and lay health workers. • Treatment development workshops to develop the intervention.
Assessing acceptability and feasibility of the intervention.	Case series with experts and lay counsellors.
Fine tuning the procedures for the evaluation of the intervention.	Pilot RCT comparing the intervention against a control

The aim of this programme was to develop a brief therapy for harmful drinking and not a brief intervention (BI). BIs involve a brief conversation lasting 5-15 minutes and consists of up to five sessions used to provide more immediate attention to clients to reduce the risk of harm due to continued substance use. This is done through one or more of feedback about personal risk, explicit advice to change, emphasis on client's responsibility for change, and providing a variety of skills to effect change using an empathetic style and increasing the client's perception of self-efficacy. On the other hand brief therapies have more and longer sessions than BIs, focus on specific behavioural change and provide clients with tools to change basic attitudes and skills to deal with substance use related problems. As people with harmful drinking have gone beyond the 'at risk' stage and already developed problems secondary to their drinking a brief therapy would be more appropriate compared to BI.

1.12 Setting

The two sites for data collection were Goa and Satara (for some steps) in India. Goa is a small state on the west coast of India. One of India's smallest states, the population of Goa is just over 1.4 million people with high literacy rate (89%) as compared to the national average (73%) (Government of India, 2011) and a gender ratio of 973 females for every 1000 males. Satara is a small district in the state of Maharashtra with a population of 3 million, with a gender ratio of 986 females for every 1000 males, and a literacy rate of 84.2%. These sites were chosen because the implementing organisation, Sangath, was based in Goa and its partner organisation was based in Satara. Both these study sites represented socio-demographically different settings and this allowed the developing psychosocial intervention to be contextually informed by such diversity, thus increasing the generalisability of the outcomes.

1.13 Developing mental health interventions

The intervention development work that is described in my thesis draws on three sources as follows: a) the intervention 'development' and 'feasibility/piloting' stages of the Medical Research Council (MRC) framework, b) the experiences of the investigators group in developing and testing a range of psychosocial interventions in this particular study setting, and c) a systematic

review of methods and outcomes of adaptations in psychosocial interventions for depressive disorders.

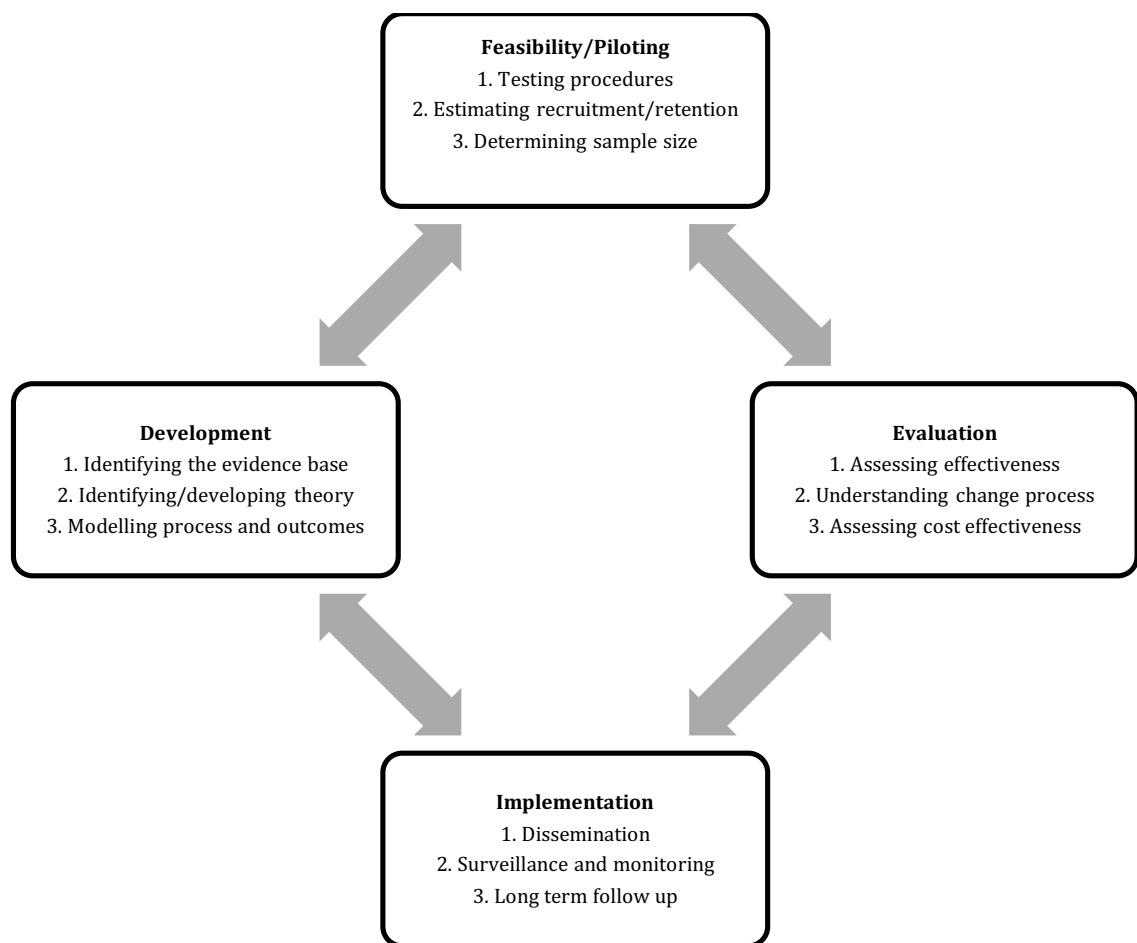
1.13.1 The MRC framework

Consistent with the MRC UK definition of ‘complex interventions’, most mental healthcare interventions are ‘complex interventions’ as they are made up of biological, psychological and social components that work independently and also interdependently with the other components to achieve the desired outcome (MRC, 2000). Mental healthcare interventions also possess other characteristics of ‘complex interventions’ such as targeting of multiple outcomes (e.g. depressive symptoms, quality of life), multiple providers delivering various levels of the intervention (e.g. Psychiatrists, General Practitioners, lay counsellors), and a range of behaviours required of the delivery agents (e.g. monitoring of symptoms, networking with primary care providers).

In 2000, the MRC published the *Framework for the Development and Evaluation of RCTs for Complex Interventions to Improve Health*, a systematic, rigorous and replicable methodology to help keep track of the research process (Campbell et al., 2000) (<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372>).

Over time the limitations of this framework became apparent and it was consequently updated and revised in 2008. The main stages and the key functions and activities at each stage of the MRC framework are as follows: Development; Feasibility/piloting; Evaluation; and Implementation (Figure 1.1) (Craig et al., 2008).

Figure 1.1: Key elements of the development and evaluation process
(Reproduced from www.mrc.ac.uk/complexinterventionsguidance).



The MRC framework describes the following steps for intervention development and testing:

1. 'Developing a complex intervention' involves identifying the evidence base, identifying or developing appropriate theory and modelling process and outcomes. The evidence base is identified by finding a recent high quality review or, in the absence of one, conducting one that is specifically designed to answer questions relevant to the intervention being developed. The next step is to identify or develop an appropriate theory by examining existing evidence and theory, and supporting it with new primary research if necessary. The final step is to model the processes and outcomes to provide information about the various components of the intervention and their interrelationships and to identify

possible weaknesses in the intervention pathway. All this data is then iteratively used to inform refinements in the intervention.

2. 'Feasibility and piloting' is then conducted to test procedures and the intervention for acceptability, estimate process indicators like the likely rates of recruitment and retention of participants, and calculate appropriate sample sizes through a mixture of qualitative (e.g. to understand acceptability of the intervention) and quantitative (e.g. to estimate retention rates) methods.
3. Finally, the intervention is evaluated using a range of randomised controlled study designs and eventually scaled up so that its advantages are accrued by larger sections of the population for whom it was originally developed.

1.13.2 Field experiences in the study setting

Over the years, Sangath (<http://www.sangath.com>), a health research NGO from Goa, India, has pioneered the use of NSHWs to deliver frontline mental health interventions for a range of mental health and developmental disorders. Sangath implemented the PREMIUM project and the intervention development process described in my thesis was informed by the intervention development processes used in Sangath to develop complex interventions for mild depression, schizophrenia, and dementia (Chatterjee et al., 2014; Dias et al., 2008; Patel et al., 2003). These interventions were developed through a scientifically documented systematic process that included identification of available systematic evidence, and testing of the acceptability and feasibility of the intervention developed through participatory methods (Balaji et al., 2012; Chatterjee et al., 2008; Dias et al., 2008).

Many of the lessons learnt in developing and testing these interventions informed the PREMIUM intervention development process. The key lesson was that persons with no professional background in mental health can effectively deliver psychosocial interventions provided that they are recruited from the local community, are given intensive participatory training, the intervention is suitably adapted to fit their skill set and designed to overcome contextual barriers, they are supervised by more experienced practitioners, and the intervention package

is integrated into existing healthcare (e.g. GP surgeries) or community platforms (e.g. women's self help groups) (Patel et al., 2011). This body of work also threw up implications for the future, which included the potential of using other members of the community as intervention delivery agents (e.g. traditional healers), the use of technology (e.g. mobile phones) to increase penetration and coverage of interventions, using a systematic methodology to identify and address barriers to acceptability and feasibility of interventions primarily designed for well resourced developed country settings, and engaging stakeholders at various levels from the early stages of intervention development to ensure subsequent successful intervention uptake (Patel et al., 2011).

1.13.3 Systematic review of adaptation of interventions for depression

The systematic review (co-authored by the author of this thesis) was conducted to describe the process, extent and nature of the adaptations and the effectiveness of the adaptations made to enhance the universal applicability of psychosocial interventions for depression developed in Western countries (Chowdhary et al., 2014). The review identified the various methods applied to adapt the psychosocial interventions. A third of the studies in the review used the MRC framework for the systematic adaptation of psychosocial interventions. This was done with the aim to increase the cultural relevance of the interventions and thus increase their acceptability, to address practical barriers to delivery e.g. shortage of trained mental health providers, to integrate the intervention within existing healthcare platforms, and to ensure efficient use of available human resources. The formative research conducted to develop culturally and contextually adapted interventions included a) selecting a theory-based psychosocial intervention (e.g. CBT) through evidence gathered from literature reviews and through consultations with various stakeholders, b) using mixed methods (quantitative and qualitative) to guide the process of development of the preliminary intervention manual and to refine the acceptability and feasibility of the intervention, and c) small controlled or uncontrolled pilot trials with trained health-care providers to deliver the preliminary version of the intervention to refine the intervention, to improve its acceptability and feasibility, and to make a preliminary estimate of the intervention to change outcomes in the target disorder. The review also found that most adaptations to the interventions were found in the dimensions of

language, context and therapist delivering the intervention. To conclude, cultural adaptations of psychosocial interventions lead primarily to adaptations in the implementation of the interventions rather than their content; and such adapted interventions are effective in populations other than those for whom the original intervention was developed.

1.14 Ethical considerations

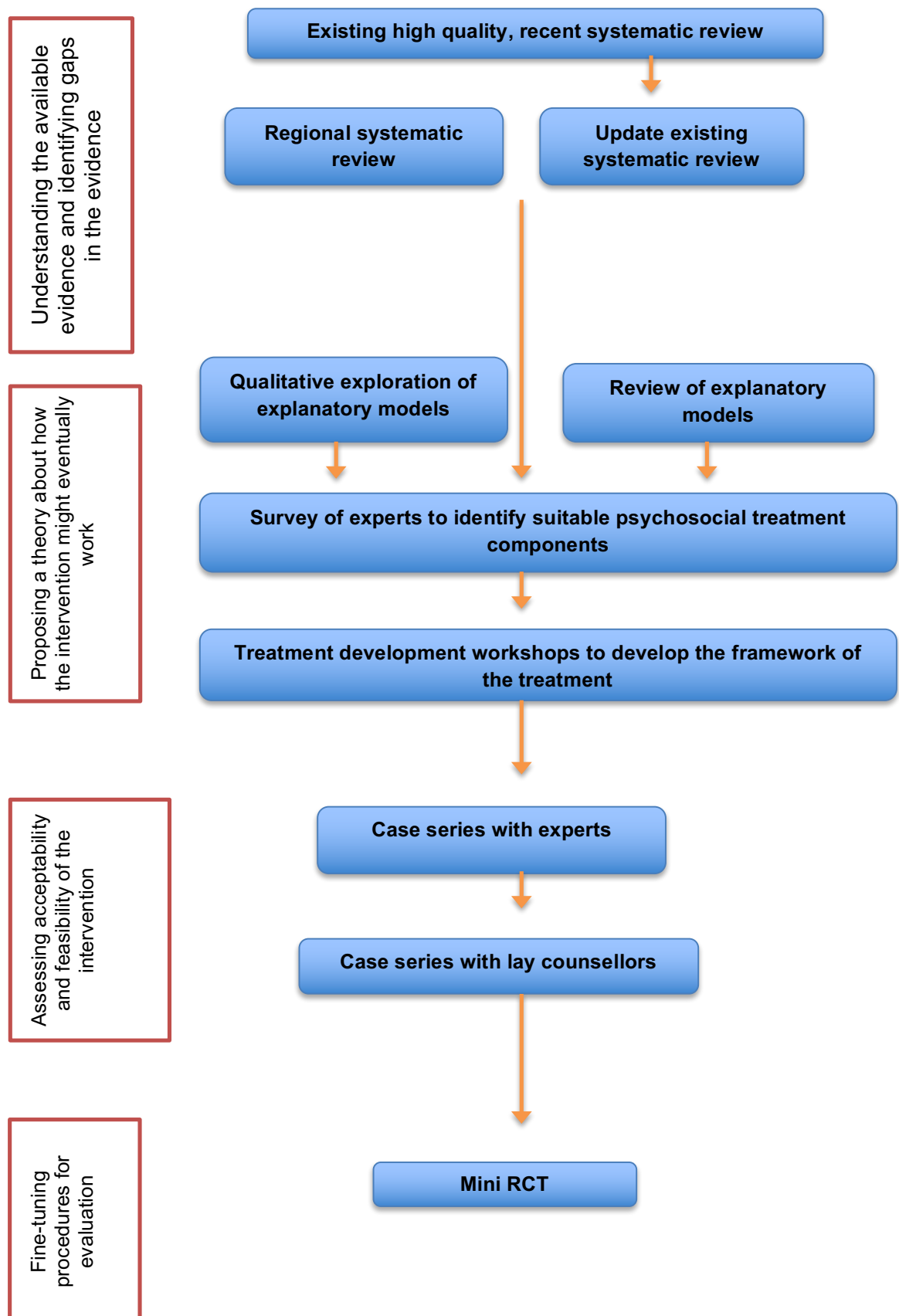
PREMIUM had received approval from the London School of Hygiene and Tropical Medicine (LSHTM) ethics committee, Sangath Institutional Review Board (IRB) and Indian Council of Medical Research (ICMR). If applicable, further details of ethical considerations specific for each step of the intervention development process have been provided in the corresponding chapter of my thesis.

1.15 Conclusion

To conclude, AUDs are one of the leading substance use disorders affecting men (Lopez et al., 2006); with profound adverse health and social impact on the drinkers, their family members and society. Although psychosocial interventions are recommended as first-line treatments for harmful drinking the evidence base is mostly derived from high-income countries, and much of it evaluates delivery by specialist providers (Benegal et al., 2009). However, variations in contextual factors, such as explanatory models of AUD, different ways of coping and dealing with mental disorders, lack of any specialist services and socio-economic determinants (such as literacy), may limit the generalisability of this evidence. Identifying effective psychosocial interventions for AUD was ranked amongst the leading research priorities for global mental health in a recent systematic priority setting exercise (Tomlinson et al., 2009) and the WHO's flagship mental health program, mhGAP, seeks to scale up evidence based packages of care for AUD, which is amongst the priority disorders selected for this initiative (WHO, 2008). The PREMIUM project aimed to develop contextually appropriate interventions for harmful drinking and depressive disorders, and the subsequent chapters of my thesis describe the formative research leading to the development of the intervention for harmful drinking and the preliminary evaluation of the intervention. The intervention was developed using a framework (Figure 1.2) that was informed by the MRC framework,

previous intervention development experiences from the study setting, and a systematic review of contextual adaptations to psychosocial interventions.

Figure 1.2: Framework for developing culturally and contextually adapted psychosocial intervention for harmful drinking



Chapter 2 Literature review of evidence based psychosocial interventions for harmful drinking[†]

2.1 Background

In Chapter 1 I described the burden of Alcohol Use Disorders (AUD), the treatment gap for AUD and the strategy of using non-specialist health workers (NSHW) to increase access to evidence based interventions. I also emphasised the need for following a systematic process of intervention development and briefly described one such framework developed by the Medical Research Council (MRC). The MRC framework states that the starting point for developing an intervention is to be fully aware of the relevant, existing evidence base. One way of doing that is to identify an existing high quality systematic review of interventions for the target condition, in this case, harmful drinking.

Sometimes, such a recent high-quality review might already be in existence, but often one may need to conduct a systematic review that is specifically designed to answer questions relevant to the intervention being developed. The existing systematic review or the new systematic review specifically conducted to inform the intervention development process should help identify previous studies that provide empirical evidence for the same or a similar intervention as the one that is being developed and/or interventions for the same or similar disorder for which the intervention is being developed.

The World Health Organization's (WHO) flagship Mental Health Gap Action Programme (mhGAP) is aimed at scaling up services for mental, neurological and substance use disorders, especially for low and middle income countries (LMIC); and has developed an intervention guide (mhGAP-IG) for these disorders to be used in non-specialist health settings (WHO, 2010b). The mhGAP-IG was informed by a systematic review of evidence of interventions that can be used by health-care providers working in non-specialized health-care settings after adaptation for national and local needs. Since PREMIUM's goal was in alignment with that of the mhGAP viz to develop an intervention that can be delivered by non-specialists in low resource settings, it was decided to

[†] Author contribution to the methods: I conducted the electronic database search, screened the search returns, extracted and analysed the data, synthesised the results, and interpreted the findings.

use and update the evidence generated by the systematic review conducted by the mhGAP programme. The aim of the review described in this chapter is to update the systematic review conducted by the mhGAP programme to identify evidence based psychosocial intervention strategies that could be used to develop a contextualized psychosocial intervention for harmful drinking to be delivered in primary care by lay counsellors. The aim of the review is not to identify only those psychosocial interventions that have been delivered by NSHW. Rather, the aim is to identify all psychosocial interventions for AUD and then filter them to separate out those that have been delivered by NSHWs.

2.2 Methods

Since the systematic review informing the mhGAP-IG involved a systematic literature search up to the year 2009, this review builds on it by covering the period from 1st January 2009 to 31st March 2011.

2.2.1 Search strategy

The following electronic databases were searched: PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) and PsycINFO (<http://www.apa.org/pubs/databases/psycinfo/index.aspx>). The following search terms were used as text words and MESH terms: (Alcohol* OR drinking OR addiction) AND (psycho* OR therapy OR counseling OR counselling OR treatment) NOT (pharma* OR medic*).

The titles of the papers identified through the database search were then double screened for eligibility and the abstracts of relevant papers retrieved. Thereafter these abstracts were examined for possible inclusion and full texts of selected papers were retrieved. These full texts were then examined to determine their compliance with eligibility criteria described below and summarized in Table 2.1. Bibliographies of selected papers were examined to find any eligible studies that might not have been identified through the database search.

2.2.2 Eligibility criteria

Only randomised controlled trials (RCT) were included. Observational studies (surveys, case control studies, cohort studies, case series) and pilot studies, even if they were designed as RCTs, were excluded. Only papers published in

English were included as there was no language expertise within the team to review papers published in non-English languages. Only studies conducted in adults (19 years and above) were included as the intervention being developed was for adults. Studies conducted in exclusively female samples were excluded as the intervention being developed was only for males. Although the intervention was being developed for harmful drinking, studies in samples that had both harmful and dependent drinkers were included, as most studies testing interventions for harmful drinkers do not exclude dependent drinkers. Similarly if the sample was described as hazardous drinkers but also included harmful drinkers (e.g. a score of >8 on the Alcohol Use Disorders Identification Test) then the study was included. Studies with harmful drinking comorbid with other substance use disorder, physical health problem or mental health problem were included. Studies with binge drinkers, purely hazardous drinkers, and purely dependent drinkers were excluded. Studies testing any psychosocial intervention by itself or in combination with a pharmacological intervention were included. Studies testing purely pharmacological interventions were excluded. Studies testing psychosocial interventions delivered on a computer or Internet based interventions were excluded as the penetration and coverage of such technologies is low in India and thus such interventions are not presently contextually relevant.

Table 2.1: Eligibility criteria for the literature review

	Inclusion criteria	Exclusion criteria
Type of study	Randomised controlled trials (RCT).	<ul style="list-style-type: none"> • Observational studies. • Pilot studies with RCT design.
Publication language	English language.	
Participants	Adults (19 years and above).	<ul style="list-style-type: none"> • Children and adolescents. • Exclusively female samples.
Disorder	<ul style="list-style-type: none"> • Harmful drinking with or without dependent drinkers in the sample. • Hazardous drinking with harmful drinkers in the sample. • Harmful drinking comorbid with any other substance use disorder or mental or physical disorder. 	<ul style="list-style-type: none"> • Purely hazardous drinking sample which excluded harmful drinkers. • Purely dependent drinkers. • Binge drinking.
Intervention	<ul style="list-style-type: none"> • Psychosocial intervention. • Psychosocial intervention combined with pharmacological intervention. 	<ul style="list-style-type: none"> • Purely pharmacological intervention. • Computer/internet based interventions.
Comparison group	<ul style="list-style-type: none"> • Treatment as usual. • No treatment. • Enhanced usual care. 	

	Inclusion criteria	Exclusion criteria
	<ul style="list-style-type: none"> • Alternative psychosocial intervention. • Pharmacological intervention. 	

All the systematic reviews identified in this literature search were also used as supplementary source of evidence.

2.2.3 Data extraction and analyses

The data from included papers were extracted into a priori designed and structured data extraction sheets. The information extracted included: country, setting, sample size, population group, intervention, comparison group, intervention delivery details including intervention techniques, number and frequency of sessions, therapist qualifications, alcohol outcome measures, and results.

The quality of each RCT was assessed for adequacy of randomization, blinding and attrition using the Jadad criteria (Jadad et al., 1996). The total Jadad score can range from 0 to 5. One point is given for each of the following criteria:

1. Study described as randomised,
2. Method of randomisation was appropriate,
3. Study described as double blind,
4. Method of double blinding was appropriate, and
5. Description of withdrawals/drop outs was provided.

One point is deducted if the method of randomisation was inappropriate or the method for double blinding was inappropriate.

Data extraction and quality assessment were conducted by two reviewers and consultation sought from the PI of PREMIUM when necessary. The appropriate statistical tests have been presented in the results.

The data were analysed qualitatively and studies were examined with regards to 1) evidence of effectiveness, and 2) generalisability to low resource settings, the two aspects that have been described in the GRADE approach (Guyatt et al., 2008) used in developing the mhGAP-IG. Four criteria were used to assess the generalisability of the evidence as follows:

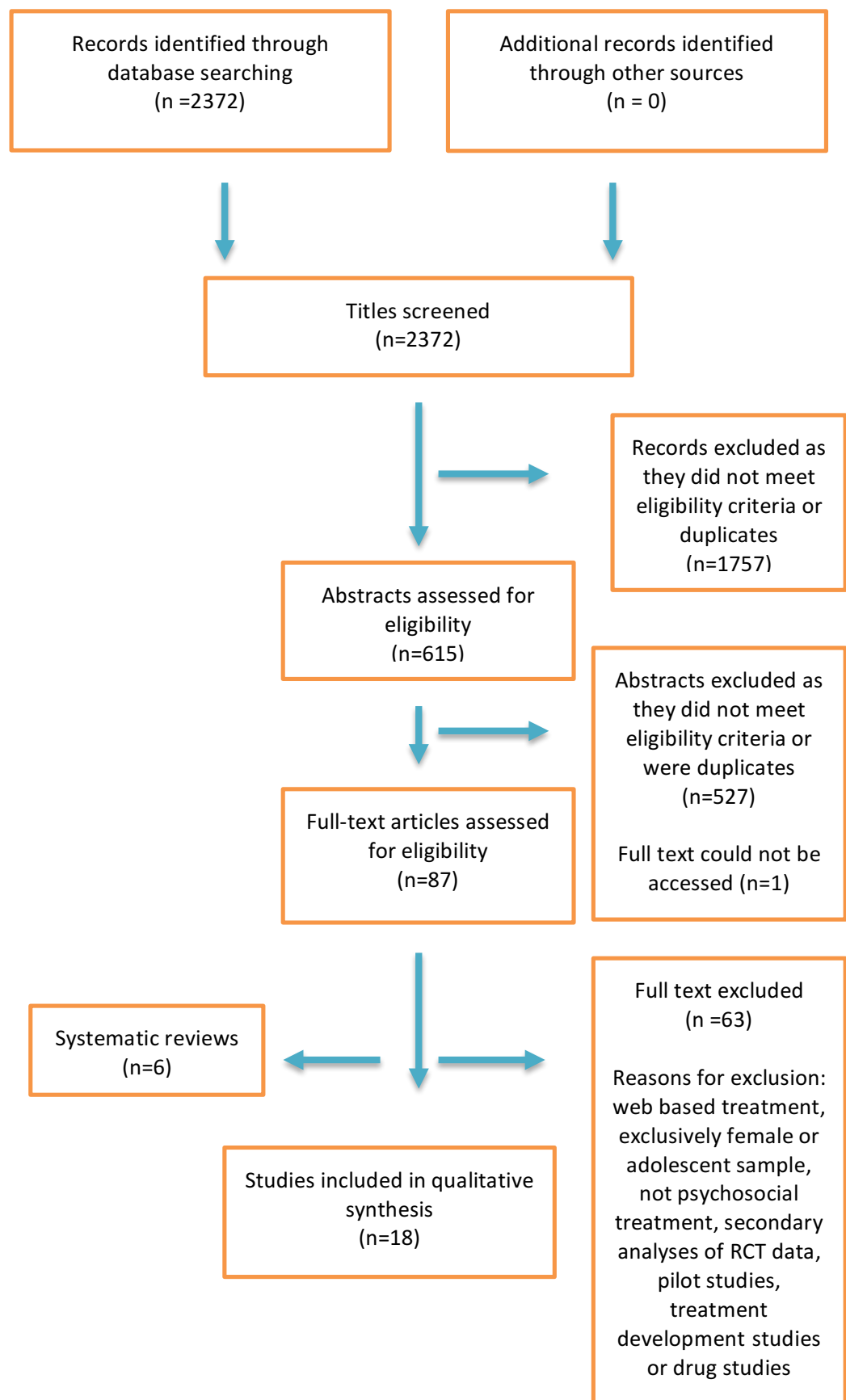
1. Was the study conducted in a primary care setting?

2. Was the study conducted in a LMIC?
3. Was the study carried out with an ethnic minority sample?
4. Was the psychosocial intervention delivered by NSHWs?

2.3 Results

The electronic database search returned 2372 studies. 1757 were not relevant, as they did not fit the eligibility criteria for the review. 615 abstracts were retrieved of which 527 were either not relevant to our review or were duplicates. 88 studies were identified for full text retrieval. Of these, one could not be retrieved. 87 were retrieved and assessed for eligibility. 63 were excluded as the intervention was web based, sample was exclusively female or adolescent, intervention was not a psychosocial intervention, or the papers described secondary analyses of RCT data, pilot studies, intervention development studies or drug studies (Figure 2.1). In all 18 RCTs (Bager and Hendrik, 2010; Baker et al., 2010; Barrowclough et al., 2010; Bernstein et al., 2010; Brown et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Field et al., 2010; Gregory et al., 2010; Gwaltney et al., 2011; Hermansson et al., 2010; Kavanagh and Connolly, 2009; Liu et al., 2011; Noknoy et al., 2010; Roudsari et al., 2009; Sobell et al., 2009; Tsai et al., 2009; Witkiewitz and Bowen, 2010) were included in this review. 6 systematic reviews (Kaner et al., 2009; Kaner et al., 2011; Magill and Ray, 2009; Moreira et al., 2009; Riper et al., 2009; Webb et al., 2009) were also identified as supplementary evidence.

Figure 2.1: Flow diagram of studies included in the systematic review



Of the RCTs, only 1 RCT was conducted in LMIC (Thailand) (Noknoy et al., 2010). The rest were conducted in the following high income countries (HIC): eight in the USA (Bernstein et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Field et al., 2010; Gregory et al., 2010; Gwaltney et al., 2011; Roudsari et al., 2009; Witkiewitz and Bowen, 2010), two each in Taiwan (Liu et al., 2011; Tsai et al., 2009), Canada (Brown et al., 2010; Sobell et al., 2009), and Australia (Baker et al., 2010; Kavanagh and Connolly, 2009), and one each in the UK (Barrowclough et al., 2010), Denmark (Bager and Hendrik, 2010), and Sweden (Hermansson et al., 2010).

2.3.1 Types of psychosocial interventions

The psychosocial interventions can be classified as 'Brief Interventions' (if described as such in the respective papers) and 'Other interventions'.

- A. Brief interventions (BI): Twelve RCTs evaluated BIs. The BIs in the RCTs were variously described as Motivational Enhancement Therapy (MET) (Carroll et al., 2009; Noknoy et al., 2010), Brief Motivational Intervention (BMI) (Bager and Hendrik, 2010; Bernstein et al., 2010; Brown et al., 2010; Field et al., 2010), BI (Baker et al., 2010; Hermansson et al., 2010; Liu et al., 2011; Roudsari et al., 2009; Tsai et al., 2009), and Motivational Interviewing (MI) (Gwaltney et al., 2011).

The BIs used the following strategies:

- a. MI based: Techniques that were commonly described in these interventions included exploring the pros and cons of drinking (Bernstein et al., 2010; Field et al., 2010; Noknoy et al., 2010), reflection (Liu et al., 2011; Noknoy et al., 2010), rolling with resistance (Brown et al., 2010), empathic interviewing (Brown et al., 2010; Liu et al., 2011), promoting self efficacy (Brown et al., 2010; Field et al., 2010; Noknoy et al., 2010), individualized feedback (Baker et al., 2010; Bernstein et al., 2010; Brown et al., 2010; Hermansson et al., 2010; Liu et al., 2011; Noknoy et al., 2010), working with ambivalence around drinking (Brown et al., 2010; Noknoy et al., 2010), and eliciting and facilitating change (Baker et al., 2010; Bernstein et al., 2010; Brown et al., 2010; Field et al., 2010; Liu et al., 2011; Noknoy et al.,

2010; Roudsari et al., 2009).

- b. Counselling and advice: Risky drinkers in one study were given simple advice that consisted of feedback on their Alcohol Use Disorders Identification Test (AUDIT) score, alcohol-related information, establishing a goal to change drinking behaviours, and advice to limit their drinking (Tsai et al., 2009).

B. Other interventions: These were further classified into the following groups:

- a. Based on cognitive and/or behaviour therapy principles: This included RCTs of Behavioural Couples Therapy (BCT) with Individual Based Therapy (IBT) (Fals-Stewart et al., 2009), integrated MI and CBT (Barrowclough et al., 2010), individual Guided Self Change (GSC) (Sobell et al., 2009) and Mindfulness Based Relapse Prevention (MBRP) (Witkiewitz and Bowen, 2010).
- b. Alternative delivery methods: Correspondence Treatment (Kavanagh and Connolly, 2009).
- c. Miscellaneous: Dynamic Deconstructive Psychotherapy (DDP) (Gregory et al., 2010).

2.3.2 Controls

In the RCTs, there were three broad categories of control groups as follows:

(a) Treatment as usual (TAU) (Bager and Hendrik, 2010; Barrowclough et al., 2010; Bernstein et al., 2010; Carroll et al., 2009; Field et al., 2010; Liu et al., 2011; Noknoy et al., 2010; Roudsari et al., 2009; Tsai et al., 2009) variously described as counselling as usual (CAU), standard care, no treatment/intervention, usual care (UC), and 'TAU'.

(b) Information/education described as information and non specific advice (Brown et al., 2010), and

(c) Active comparators which included BI followed by a further nine 1-hour sessions with (ii) an alcohol focus; (iii) a depression focus; or (iv) an integrated

focus (Baker et al., 2010), minimally assessed control (MAC) (Bernstein et al., 2010), standard assessed control (Bernstein et al., 2010), 'comprehensive intervention' (Hermansson et al., 2010), personalised feedback only (FO) (Gwaltney et al., 2011), IBT (Fals-Stewart et al., 2009), self-monitoring forms and letters summarising progress followed by delayed correspondence treatment (Kavanagh and Connolly, 2009), Group GSC (Sobell et al., 2009) and 'optimized community care' (OCC) (Gregory et al., 2010).

2.3.3 Setting

Four RCTs were conducted in specialist addiction/mental health services (Barrowclough et al., 2010; Carroll et al., 2009; Gregory et al., 2010; Sobell et al., 2009), three in primary care (Fals-Stewart et al., 2009; Kavanagh and Connolly, 2009; Noknoy et al., 2010), eight in hospital wards or emergency room (ER) (Bager and Hendrik, 2010; Bernstein et al., 2010; Field et al., 2010; Gregory et al., 2010; Gwaltney et al., 2011; Liu et al., 2011; Roudsari et al., 2009; Tsai et al., 2009), one in a combination of community and primary/secondary care setting (Baker et al., 2010) and two in the community (Brown et al., 2010; Hermansson et al., 2010).

2.3.4 Sample

The sample sizes ranged from 48 (Fals-Stewart et al., 2009) to 1493 (Field et al., 2010; Roudsari et al., 2009).

In the RCTs, the alcohol consumption criteria for inclusion in the study, included a range of AUDs (Bager and Hendrik, 2010; Baker et al., 2010; Barrowclough et al., 2010; Bernstein et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Field et al., 2010; Gregory et al., 2010; Kavanagh and Connolly, 2009; Liu et al., 2011; Noknoy et al., 2010; Sobell et al., 2009; Tsai et al., 2009), biological parameters indicating alcohol abuse (Field et al., 2010; Gwaltney et al., 2011; Hermansson et al., 2010; Roudsari et al., 2009), screening tool results (Bernstein et al., 2010; Brown et al., 2010; Field et al., 2010; Gwaltney et al., 2011; Hermansson et al., 2010; Roudsari et al., 2009), quantity and frequency measures (Kavanagh and Connolly, 2009; Roudsari et al., 2009), and effects of alcohol use (Bernstein et al., 2010; Brown et al., 2010; Field et al., 2010; Roudsari et al., 2009).

Many RCTs had participants who were recruited if they fulfilled one of many criteria (e.g. CAGE positive or injuries secondary to drinking). Such RCTs were included in the review if at least one of the eligibility criteria of the RCT met the main inclusion criteria for the review (i.e. harmful drinking). Harmful drinking as eligibility criteria in the various RCTs included alcohol abuse (Carroll et al., 2009; Fals-Stewart et al., 2009; Gregory et al., 2010), problem drinking (Tsai et al., 2009), harmful use (Bager and Hendrik, 2010), hazardous drinking (included harmful drinking) (Baker et al., 2010; Noknøy et al., 2010), unhealthy alcohol use (Liu et al., 2011), DSM IV alcohol disorder (Kavanagh and Connolly, 2009), alcohol misuse (Barrowclough et al., 2010), primary alcohol problem (PAP) (Sobell et al., 2009), AUDIT score >8 (Bernstein et al., 2010; Brown et al., 2010; Gwaltney et al., 2011; Hermansson et al., 2010) and CAGE positive (Field et al., 2010; Roudsari et al., 2009).

Besides harmful drinking the samples from the various RCTs also had participants which fulfilled the following criteria as well: alcohol dependence (Barrowclough et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Gregory et al., 2010), Blood Alcohol Concentration (BAC) positive (Field et al., 2010; Gwaltney et al., 2011; Roudsari et al., 2009), abnormal Carbohydrate Deficient Transferrin (CDT) (Hermansson et al., 2010), drinking above a prescribed limit of safe drinking (Kavanagh and Connolly, 2009; Roudsari et al., 2009), driving under the influence of alcohol (Brown et al., 2010), injuries after drinking alcohol (Field et al., 2010; Roudsari et al., 2009) and high risk behaviours after drinking alcohol (Bernstein et al., 2010).

2.3.5 Therapist Qualifications

In the RCTs the interventions were delivered by therapists with Bachelor's degree (Bernstein et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Gwaltney et al., 2011; Roudsari et al., 2009; Sobell et al., 2009), Master's degree (Bernstein et al., 2010; Carroll et al., 2009; Fals-Stewart et al., 2009; Field et al., 2010; Gwaltney et al., 2011; Roudsari et al., 2009; Witkiewitz and Bowen, 2010), health professionals like doctors (Gregory et al., 2010), nurses (Bager and Hendrik, 2010; Barrowclough et al., 2010; Hermansson et al., 2010; Noknøy et al., 2010; Tsai et al., 2009), psychologists (Baker et al., 2010; Barrowclough et al., 2010), and social workers (Bager and Hendrik, 2010;

Barrowclough et al., 2010; Liu et al., 2011), associate (undergraduate degree awarded in USA and equivalent to the first 2 years of a 4 year college degree) or high school degrees (Carroll et al., 2009), and graduate student (Brown et al., 2010).

2.3.6 Alcohol use outcomes

In the RCTs included in this review, the outcomes measured included quantity and frequency of drinking, and changes in alcohol use (Baker et al., 2010; Barrowclough et al., 2010; Bernstein et al., 2010; Brown et al., 2010; Fals-Stewart et al., 2009; Field et al., 2010; Gregory et al., 2010; Gwaltney et al., 2011; Kavanagh and Connolly, 2009; Liu et al., 2011; Noknoy et al., 2010; Sobell et al., 2009; Witkiewitz and Bowen, 2010), AUDIT scores (Hermansson et al., 2010; Tsai et al., 2009), biological markers (Brown et al., 2010; Hermansson et al., 2010) and consequences of alcohol consumption (Bernstein et al., 2010; Roudsari et al., 2009). The commonest quantity and frequency outcome was volume of alcohol or drinks per week (Baker et al., 2010; Field et al., 2010; Kavanagh and Connolly, 2009; Liu et al., 2011; Noknoy et al., 2010). Other quantity and frequency outcomes that were measured included maximum amount/drinks consumed in one day (Baker et al., 2010; Field et al., 2010) and percentage days of heavy drinking (Fals-Stewart et al., 2009; Field et al., 2010), average drinks per drinking day (Sobell et al., 2009), heavy episodic drinking (Gregory et al., 2010), number of days of drinking in a week (Kavanagh and Connolly, 2009; Liu et al., 2011), average drinking days/week (Baker et al., 2010), daily alcohol consumption (Baker et al., 2010), per cent of risky drinking days (Brown et al., 2010), number of heavy drinking episodes (Liu et al., 2011), average drinking per drinking day (Noknoy et al., 2010), hazardous drinking per drinking day (Noknoy et al., 2010), hazardous drinking per week (Noknoy et al., 2010), and heavy drinking days (Gwaltney et al., 2011).

Biological markers measured in the RCTs included in this review included Gamma Glutamyl Transferase (GGT) (Brown et al., 2010; Hermansson et al., 2010), Alanine Transaminase (ALT) (Brown et al., 2010), Aspartate Aminotransferase (AST) (Brown et al., 2010), Mean Corpuscular Volume (MCV) (Brown et al., 2010) and CDT (Hermansson et al., 2010). Consequences of alcohol consumption, measured in one study were injuries (Roudsari et al.,

2009). Other miscellaneous outcomes that were measured included mean days enrolled in treatment (Carroll et al., 2009), and intention to quit using alcohol (Bernstein et al., 2010).

2.3.7 Level of evidence (Jadad criteria)

Two RCTs scored 3 (Brown et al., 2010; Hermansson et al., 2010), 10 scored 2 (Bager and Hendrik, 2010; Baker et al., 2010; Barrowclough et al., 2010; Bernstein et al., 2010; Carroll et al., 2009; Kavanagh and Connolly, 2009; Liu et al., 2011; Noknoy et al., 2010; Roudsari et al., 2009; Witkiewitz and Bowen, 2010) and six scored 1 (Fals-Stewart et al., 2009; Field et al., 2010; Gregory et al., 2010; Gwaltney et al., 2011; Sobell et al., 2009; Tsai et al., 2009).

All studies were described as 'RCT's and most adequately randomized the participants. Although some studies were described as double blind (and consequently scored one point), they could not score a point on 'appropriate double blinding' as the very nature of a psychosocial intervention preclude blinding of participants. Finally, most of the studies did not provide any description of dropouts and withdrawals.

Details of the RCTs included in this review are described in Table 2.2. Details of the various psychosocial interventions in the RCTs are described in Table 2.3

Table 2.2: International review of effectiveness of psychosocial interventions for alcohol use disorders (Randomised Controlled Trials)

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
BRIEF INTERVENTIONS								
Carroll et al (2009), USA	Specialist substance abuse programs	Masters, Bachelor's, Associates or High School degrees	Alcohol abuse or dependence	436	Motivational Enhancement Therapy (MET)	Counselling as usual (CAU)	Mean days enrolled in treatment	2
Roudsari et al (2009), USA	Urban trauma centre	Masters or 'degreed'	<ul style="list-style-type: none"> ▪ BAC positive ▪ Self-reported drinking within 6 hours before 	1493	Brief Intervention (BI)	Standard care	<ul style="list-style-type: none"> ▪ All-type injuries ▪ Alcohol-related injuries ▪ Injuries that required ER or 	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
			injury <ul style="list-style-type: none"> ▪ CAGE positive ▪ >5 drinks per occasion (men), >4 drinks per occasion (women) 				hospital visits	
Tsai et al (2009), Taiwan	Medical/surgical units	Psychiatric nurses with medical experience	Problem drinkers	389	BI	No treatment	AUDIT score	1
Bager et	Medical unit	Nurses,	Harmful use	50	Brief	Usual Care	Alcohol abstinence	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
al (2010), Denmark		Social workers			motivational interviewing (BMI)	(UC)		
Baker et al (2010), Australia	Self referral and referral by health professionals	Psychologists	Hazardous drinking	284	BI	BI followed by a further nine 1-hour sessions with (ii) an alcohol focus; (iii) a depression focus; or (iv) an integrated focus.	<ul style="list-style-type: none"> Average drinking days per week Maximum alcohol consumption on single day Daily alcohol consumption Mean drinks per week 	2
Bernstein et al (2010), USA	Emergency Room (ER)	Bachelor's degree	<ul style="list-style-type: none"> Binge drinking High-risk 	853 (>85% were >18)	BMI	Minimally assessed control (MAC)	<ul style="list-style-type: none"> Abstinence Change in pattern 	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
			behaviours in conjunction with alcohol use ▪ AUDIT >8	years old)		Standard assessed control (AC)	of alcohol use ▪ Intention to quit using ▪ Cutback on use, or change the circumstances of use ▪ Reduction of consequences of alcohol use	
Brown et al (2010),	Community	Graduate students	▪ Convicted of at least 2	▪ 197	BMI	Information and non	▪ Per cent of risky drinking days	3

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
Canada			Driving While Impaired (DWI) offences <ul style="list-style-type: none"> AUDIT >8 			specific advice	<ul style="list-style-type: none"> Mean change in per cent of risky drinking days Biomarkers-ALT, AST, GGT, MCV 	
Field et al (2010), USA	Urban trauma centre	Master's or graduate degrees	Sequential criteria: <ul style="list-style-type: none"> Alcohol intoxication or alcohol use or positive BAC; Self-reported 	1493	BMI	Treatment as usual (TAU)	<ul style="list-style-type: none"> Volume/week Maximum number of standard drinks consumed in one day Typical quantity consumed Percentage days 	1

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
			drinking 6 hours prior to injury; (iii) at-risk drinking; or <ul style="list-style-type: none"> CAGE + 				abstinent <ul style="list-style-type: none"> Percentage days heavy drinking 	
Hermans son et al (2010), Sweden	Community	Occupation al health nurses	<ul style="list-style-type: none"> AUDIT >8 Carbohydrate Deficient Transferrin (CDT) above reference range 	194	BI	<ul style="list-style-type: none"> No intervention Comprehensive intervention 	<ul style="list-style-type: none"> AUDIT Biomarkers (CDT, GGT) 	3
Noknøy et	Primary care	Nurse	Hazardous	117	Motivational	Assessment	<ul style="list-style-type: none"> Average drinking 	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
al (2010), Thailand			drinking (AUDIT >8)		Enhancement Therapy (MET)	only (AO)	<p>per drinking day during the previous week</p> <ul style="list-style-type: none"> ▪ Hazardous drinking per drinking day during the previous week ▪ Average drinking per week during the previous week ▪ Hazardous drinking per week during the previous week 	

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
Gwaltney et al (2011), USA	ER	Master's or Bachelor's degree	<ul style="list-style-type: none"> BAC > 0.01%, Alcohol in the 6 h prior to the event that precipitated their ER visit AUDIT > 8 	198	MI	Personalised feedback only (FO)	Heavy drinking days	1
Liu et al (2011),	Medical/surgical units	Social workers	<ul style="list-style-type: none"> Heavy drinking, 	616	BI	UC	<ul style="list-style-type: none"> Weekly alcohol 	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
Taiwan			<p>defined as more than 14 drinks per week without meeting the criteria for alcohol abuse or dependence,</p> <ul style="list-style-type: none"> ▪ Alcohol abuse ▪ Alcohol dependence 				<p>consumption</p> <ul style="list-style-type: none"> ▪ Number of days of drinking in a week ▪ Number of heavy drinking episodes 	

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
			e.					
OTHER INTERVENTIONS								
Fals-Stewart et al (2009), USA	Primary care	Masters or bachelors degree	Alcohol abuse or dependence	52 (Gay) 48 (Lesbian)	Behavioural couples therapy (BCT) plus individual-based treatment (IBT)	IBT	Per cent days of heavy drinking	1
Kavanagh (2009), Australia	Primary care and community	Not specified	<ul style="list-style-type: none"> Weekly consumption >280 g (men), >140 g (women) Alcohol disorder 	204	Correspondence Treatment	Self-monitoring forms and letters summarising progress followed by delayed correspondence treatment	<ul style="list-style-type: none"> Mean weekly consumption Mean drinking days per week 	2

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
			(DSMIV)					
Sobell et al (2009), Canada	Specialist substance use program	Bachelors and above	Primary alcohol problem (PAP)	287	Individual Guided Self Change (GSC)	Group GSC	Standard drinks/drinking day	1
Barrowclough et al (2010), UK	Specialist mental health services	Psychologists Nurse therapists Social worker	Alcohol/drug dependence/mi suse	327	Integrated MI and Cognitive Behaviour Therapy (CBT)	Standard care	Frequency and amount of substance use	2
Gregory et al	ER, specialist	Psychiatry residents	Alcohol abuse /dependence	30	Dynamic Deconstructive	Optimized community	Heavy drinking (>5 drinks/occasion)	1

Author (Year), Country	Setting	Therapist	Population	Sample Size	Intervention	Comparison	Alcohol Outcomes	Level of evidence (Jadad)
(2010), USA	mental health services, specialist substance use programs				Psychotherapy (DDP)	care (OCC).		
Witkiewitz et al (2010), USA	Specialist substance use program	Masters degree in psychology or social work	Completed intensive outpatient or inpatient treatment within the previous 2 weeks	168	Mindfulness Based Relapse Prevention (MBRP)	TAU	Total days of use during the 60 days	2

Table 2.3: Details of psychosocial interventions from the RCTs included in the international review

Psychosocial intervention	Description
BRIEF INTERVENTIONS	
Brief Interventions (BI) based on Motivational Interviewing (MI)	<p>BI based on MI use a “non-confrontational, patient-centred conversation” focused on patients’ drinking pattern, with the purpose of encouraging them to change risky drinking. The sessions include elements like the following:</p> <ul style="list-style-type: none"> • Exploring drinking patterns; • Discussing ambivalence around drinking; • Evoking hypothetical changes in drinking patterns; • Developing a plan for change; • Offering brief feedback, information, and norms, specific to age and gender; • Exploring pros and cons of alcohol consumption while eliciting “change talk”; • Using the ‘Readiness to Change Ruler’ to reinforce movement toward behaviour change; • Generating a menu of options and negotiating appropriate goals;

Psychosocial intervention	Description
	<ul style="list-style-type: none"> • Calling up assets and instilling hope; • Discussing barriers to change; • Promoting self-efficacy; • Allowing flexibility in strategies; • Rolling with resistance; • Acknowledging the drinker's responsibility for changing drinking behaviours; • Providing support for any efforts or intention to quit drinking or reduce harm associated with drinking; • Questioning skills to elicit self-motivational statements; • Eliciting commitment to change.
Brief Counselling	<p>Scripted intervention workbook which included</p> <ul style="list-style-type: none"> • Review of alcohol- related health effects; • Pie chart displaying the frequency of different types of at-risk drinkers;

Psychosocial intervention	Description
	<ul style="list-style-type: none"> • List of methods for cutting down drinking; • Treatment contract; • Cognitive behavioural exercises.
OTHER INTERVENTIONS	
Individual Behavioural Therapy (IBT)	<ul style="list-style-type: none"> • 32 sessions of individual, 12-step facilitation; • Sessions derived from the Individual Drug Counselling (IDC) manual modified to focus on alcohol; • Based on the concept that alcoholism is a spiritual and medical disease, consistent with the philosophy of Alcoholics Anonymous (AA); • Patients encouraged to achieve and maintain abstinence from alcohol and other psychoactive substances and also to attend AA self-help support groups.
Behavioural Couples Therapy (BCT)	<p>Patient and partner attended 12 BCT intervention sessions together and patient attended 20 sessions of IBT (described above);</p> <p>The BCT sessions had two main components:</p>

Psychosocial intervention	Description
	<ul style="list-style-type: none"> • Substance-focused component: This included ‘(a) a recovery contract with a calendar to record AA meetings attended, drug urine screen results, and completion of a daily “trust discussion” in which the patient states an intent to stay abstinent that day and the spouse expresses support for the patient's efforts; (b) teaching partners to decrease behaviours that may trigger or enable substance use; and (c) helping the couple decrease the patient's exposure to alcohol and drugs by removing alcohol from the home and avoiding or managing alcohol- related family and social gatherings’; • Relationship-focused component that sought to increase positive feelings, shared activities, and constructive communication.
Correspondence Treatment	<ul style="list-style-type: none"> • Based on the principles of cognitive therapy; • Emphasises risks for alcohol misuse from negative emotions more than other high-risk situations; • Comprised of eight newsletters with accompanying progress letters and worksheets: <p>Newsletter 1: Motivation enhancement and establishment of an alcohol goal, identifying potentially difficult situations for alcohol control, and developing solutions.</p> <p>Newsletter 2: Introduces cognitive therapy and begins work on overly positive alcohol</p>

Psychosocial intervention	Description
	<p>expectancies.</p> <p>Newsletter 3: Describes thought challenging.</p> <p>Newsletter 4: Describes strategies to address craving.</p> <p>Newsletter 5: Covers social skills</p> <p>Newsletter 6: Applies problem solving to a current issue.</p> <p>Newsletter 7: Covers problem solving, maintenance of social supports and development of non- alcohol interests.</p> <p>Newsletter 8: Focuses on relapse prevention.</p>
Guided Self Change (GSC)	<p>The major intervention components were: (a) personalised feedback, (b) decisional balancing, (c) treatment goal advice for patients selecting their own goal, (d) MI interactional style, (e) self-monitoring of within-treatment alcohol use, (f) brief readings and homework assignments, and (g) cognitive relapse prevention procedures.</p> <p>Both experimental conditions heard a common set of instructions for the self- monitoring component and received the daily diary forms. Then they received one of the following additional instructions based on their randomisation status:</p>

Psychosocial intervention	Description
	<p>a. Alcohol reduction (AR) instructions: “Over the next two weeks, we ask that you try to reduce the amount of alcohol that you drink by 50%. By 50% reduction, we mean you cut the number of drinks you typically drink per occasion by half in the next two weeks.”</p> <p>b. Strategy increase (SI) instruction: “Over the next two weeks, we ask that you try to increase your use of the strategies listed below by 50%. By 50% increase, we mean you increase the typical number of strategies used by half. You can use some more frequently and/or use additional strategies that you haven't yet tried.”</p>
Integrated MI and CBT	<p>Intervention had two phases as follows:</p> <p>Phase 1: Engagement; eliciting and understanding the patient’s perspective in relation to life goals; and exploring the patient’s perspectives on both substance misuse and mental health issues in relation to goals.</p> <p>Phase 2: Identifying and increasing awareness of high risk situations and warning signs for lapse or relapse; developing coping skills for handling such situations; coping with cravings and urges; making lifestyle changes as alternatives to substance use; and normalising and responding to lapses and relapses.</p>
Dynamic Deconstructive Psychotherapy	<ul style="list-style-type: none"> Establishing and maintaining the therapeutic alliance through collaboratively establishing explicit treatment contract, providing psycho-education, empathy, and mirroring, and de-

Psychosocial intervention	Description
	<p>constructing non-reflective states that threaten the alliance;</p> <ul style="list-style-type: none"> Integrating polarized and distorted attributions towards self and others by helping identify emotions and construct sequences of recent interactions or maladaptive behaviours, asking about alternative or opposing attributions of self, others, and behaviours, providing integrative comments for polarized attributions while avoiding siding with either pole; Accepting limitations of self and others by facilitating mourning for loss of grandiosity and idealizations of significant relationships, exploring ambivalence towards intervention and recovery and experientially challenging regressions to previous levels of functioning; and Differentiating from therapist by facilitating mourning for limitations of the therapist and the intervention, providing experiential acceptance for feelings of anger, hurt, and disappointment towards the therapist and connecting past and present through interpretations.
Telephone monitoring and counselling (TMC)	Initial face-to-face session with counsellor to select goals to address in the upcoming sessions and followed by brief telephone calls for up to 18 months. Each call consisted of a structured 10-item assessment of current substance use status, other risk factors (e.g., craving, low self efficacy, depression), and protective factors (e.g., attendance at self-help meetings, participation in other pro-recovery social activities), which was referred to as a progress assessment. A

Psychosocial intervention	Description
	<p>scoring algorithm was used to generate three levels of risk which informed intervention strategies as follows:</p> <ul style="list-style-type: none"> • Low risk: Review of current goals and the specific objectives that needed to be accomplished to reach each goal, any problems identified in the risk assessment were also addressed, reinforcement of positive behaviours and further encouragement for involvement in pro-recovery activities. • Moderate or high risk: Identifying and rehearsing better coping responses to existing or anticipated risky situations. For those at high risk, a stepped-care component was triggered and this included more frequent telephone calls provided over several weeks and if level of risk did not drop, participants received face-to-face MI-based evaluation sessions followed by CBT.
Mindfulness Based Relapse Prevention (MBRP)	<ul style="list-style-type: none"> • MBRP combines cognitive behavioural relapse prevention program with mindfulness practice. • MBRP targets negative mood, craving, and their roles in the relapse process and offers skills in cognitive behavioural relapse prevention and mindfulness meditation. • Clients typically meditate in and out of sessions and the mindfulness practices are intended to increase discriminative awareness and acceptance, with a specific focus on

Psychosocial intervention	Description
	<p>affective and physical discomfort.</p> <ul style="list-style-type: none"> • Clients learn to observe physical, cognitive, emotional, or craving states without “automatically” reacting. Through mindfulness-based exercises, and discussion, clients practice a non-judgmental approach to negative affective states i.e. explore the emotional, physical, and cognitive components of experience, instead of attempting to escape them.
Personalised feedback	<ul style="list-style-type: none"> • Personalised feedback regarding an individual’s alcohol-consumption patterns. • Overview of the patient’s alcohol consumption, blood alcohol concentration levels (BAC); associated health and social impacts of problem drinking; or self-help strategies to change problematic alcohol consumption. • Comparing patient’s own drinking with that of his/her own cohort.
Social Norms Intervention	<ul style="list-style-type: none"> • Provide information about actual drinking norms, comparisons between the participant’s drinking pattern and the actual drinking norm and perceptions of the norm with the actual drinking norm. • The participants are given a personal drinking profile which includes quantity of alcohol consumed, average money spent on alcohol, calorie intake; their risk factors; and normative comparisons (e.g., beliefs about peers drinking, amount consumed in relation

Psychosocial intervention	Description
	to peers).

2.3.8 Effectiveness (Table 2.4)

A) Effectiveness of BI

The effectiveness of BI was evaluated in several RCTs. Compared to TAU, BMI in Hispanics led to lesser drinks/week (Effect size $d=0.14$, $p=0.01$), reduced maximum amount of alcohol consumed (Effect size $d=0.30$, $p=0.02$), and reduced percentage days of heavy drinking (Effect size $d=0.24$, $p=0.02$) (Field et al., 2010). In other RCTs, compared to usual care, BI led to a significant reduction in AUDIT scores (55.1% vs. 45.3%, $p<0.05$) (Tsai et al., 2009), and reduction in drinking days in the previous week (1.52 vs. 0.75, $p<0.05$) (Liu et al., 2011). Compared to controls, BMI led to a significantly higher proportion of abstinence (68% vs. 40% $p<0.05$) in harmful drinkers (Bager and Hendrik, 2010), greater odds of trying to quit drinking (OR 1.77; $p=0.007$), or being careful about situations for drinking (OR 1.66; $p=0.029$) (Bernstein et al., 2010), as well as greater change in MCV (9.6 fL vs. 1.75 fL, $p<0.005$) in hazardous drinkers (Brown et al., 2010). Compared to MI, FO was significantly associated with an increased likelihood of heavy drinking (OR=1.72, 95% CI=1.15–2.56, $p<0.0001$) at follow up (Gwaltney et al., 2011). Finally, compared to advice only, MET resulted in a significant ($p<0.05$) reduction in average drinking per drinking day (2.26 drinks/day vs. 4.02 drinks/day) and average drinks per week (4.72 drinks/week vs. 11.24 drinks/week) in hazardous drinkers (Noknoy et al., 2010). To summarise, BIs delivered in various formats, to persons with AUDs, are associated with a significant reduction in alcohol consumption compared to treatment as usual or active comparators.

B) Sustainability of effects of BI

Five studies of BI collected follow up outcome data at multiple time points. In these studies, the earliest follow up point was 6 weeks and no intervention effect was observed at this point (Noknoy et al., 2010). In other studies no intervention effects were apparent at 6 months (Tsai et al., 2009) but emerged at later assessment points. Studies showed sustained intervention effects from 3 to 6-month (Noknoy et al., 2010), 6 to 12 month (Field et al., 2010) and 4 to 12 months (Liu et al., 2011). Finally, in one study intervention effects were not sustained, from 6 to 12 months (Brown et al., 2010).

C) BI in patients with dual diagnoses

There was only one RCT investigating the efficacy of BI in depressed patients with AUD (Baker et al., 2010). In this study there was a differential effect of the interventions. Men reduced their drinking more if they received alcohol-focused treatment (mean change= 30.23 drinks/week vs. 18.0 drinks/week) while women reduced their drinking more if they received a depression-focused treatment (mean change=20.24 drinks/week vs. 6.82 drinks/week). Integrated treatment (for depression and AUD) resulted in a greater reduction in drinking days than single-focused treatments (for depression or AUD only) (mean change=1.83 vs. 0.92, $p=0.014$). Finally there was a greater reduction in drinking days per week after 10 sessions of treatment than BI (Mean change=1.29 vs. 0.58, $p=0.016$).

D) Effectiveness of BI in the workplace

There was only one RCT of BI delivered in the workplace. In the RCT, there were no statistically significant differences in AUDIT scores and CDT between screening and BI in workers with an AUDIT score of 8 and above (Hermansson et al., 2010).

E) Effectiveness of psychosocial interventions based on cognitive and/or behaviour therapy principles

In a RCT, BCT with IBT led to reduction of percentage days of heavy drinking at 12 months in both gay (from 41.94% at pre treatment to 18.00% at 12 months) and lesbian patients (from 38.62% at pre treatment to 15.71% at 12 months) with alcohol abuse or dependence; and this was significantly better than in IBT alone ($p < 0.05$) (Fals-Stewart et al., 2009). In the RCT of integrated MI and CBT in psychosis with substance use disorder, the odds of being in one of the more abstinent groups versus one of the less abstinent groups was higher for the intervention group than for the control group (OR 1.50, 95% CI 1.08 to 2.09; $p=0.016$) (Barrowclough et al., 2010). Finally, guided self-change (Sobell et al., 2009) and MBRP (Witkiewitz and Bowen, 2010) were not effective in reducing alcohol consumption compared to controls.

F) Effectiveness of other psychosocial interventions

One RCT compared 'correspondence treatment' delivered over month 0 to 3 (immediate correspondence treatment) with delivery over month 3 to 6 (delayed correspondence treatment) (Kavanagh and Connolly, 2009). Compared to those with 'alcohol disorder' receiving delayed correspondence treatment those provided with immediate correspondence treatment (treatment in first 3 months) showed significantly reduced mean weekly consumption from baseline to 3 months in men (immediate treatment 62.2 drinks/week to 33.7 drinks/week; delayed treatment 66.1 drinks/week to 51.4 drinks/week) and women (immediate treatment 40.8 drinks/week to 24.4 drinks/week; delayed treatment 40.7 drinks/week to 29.3 drinks/week. Finally, in an RCT comparing DDP with OCC in borderline personality disorder with AUD, the former resulted in greater reduction in per cent heavy drinking days (Effect size $d=0.39$) (Gregory et al., 2010).

2.3.9 Contextualizing the evidence to PREMIUM objectives

The eligible studies were examined using four criteria: a) Studies conducted in LMIC, b) Studies in ethnic minorities, c) Studies in primary care and d) Interventions provided by NSHW.

A) Effectiveness of psychosocial interventions for AUD in LMIC

Only one RCT was conducted in LMIC, namely Thailand (Noknoy et al., 2010). This RCT tested MET provided to hazardous drinkers by a nurse in primary care. It reported a significant ($p<0.05$) reduction in average drinking per drinking day (2.26 drinks/day vs. 4.02 drinks/day) and average drinks per week (4.72 drinks/week vs. 11.24 drinks/week) compared to control.

B) Effectiveness of psychosocial interventions for AUD in ethnic minorities

There was only one study of psychosocial intervention for AUD in ethnic minorities. Although there was a reduction in drinking in Hispanics, blacks and whites independent of treatment assignment, only among Hispanics, BMI reduced alcohol intake significantly as measured by average volume per week (Effect size $d=0.14$, $p=0.01$), percentage days heavy drinking (Effect size $d=0.24$, $p=0.02$), and maximum amount consumed in one day (Effect size $d=0.3$, $p=0.02$) (Field et al., 2010).

C) Effectiveness of psychosocial interventions for AUD in primary care

Two RCTs (Kavanagh and Connolly, 2009; Noknoy et al., 2010) were conducted in primary care. In one of them, MET provided to hazardous drinkers led to significant ($p < 0.05$) reductions in average drinking per drinking day (2.26 drinks/day vs. 4.02 drinks/day) and average drinks per week (4.72 drinks/week vs. 11.24 drinks/week) (Noknoy et al., 2010). In the other RCT testing 'correspondence treatment', compared to those with 'alcohol disorder' receiving delayed correspondence (treatment from months 3-6), those provided with immediate correspondence treatment (treatment in first 3 months) showed significantly reduced mean weekly consumption from baseline to 3 months in both men (Immediate treatment 62.2 drinks/week to 33.7 drinks/week; Delayed treatment 66.1 drinks/week to 51.4 drinks/week) and women (Immediate treatment 40.8 drinks/week to 24.4 drinks/week; Delayed treatment 40.7 drinks/week to 29.3 drinks/week) (Kavanagh and Connolly, 2009).

D) Effectiveness of psychosocial interventions for AUD delivered by NSHWs

Eight RCTs involved NSHWs delivering the psychosocial intervention (Bager and Hendrik, 2010; Bernstein et al., 2010; Brown et al., 2010; Field et al., 2010; Gwaltney et al., 2011; Hermansson et al., 2010; Liu et al., 2011; Noknoy et al., 2010). MI provided by NSHWs in a trauma centre showed no association between intervention and heavy drinking at 3 months but in the sixth month, there was significantly increased likelihood of heavy drinking in FO group compared to MI (OR=1.72, 95% CI=1.15–2.56, $p < 0.0001$) (Gwaltney et al., 2011). Similarly BI provided by a physician, nurse or social worker led to greater reductions in drinking days in the previous week in the intervention group compared to control (1.52 days vs. 0.75 days, $p < 0.05$) (Liu et al., 2011). BMI provided by nurses and social workers led to abstinence in 68% of harmful drinkers compared to 40% who received usual care ($p < 0.05$) (Bager and Hendrik, 2010). Compared to controls, BMI delivered by peer educators led to increased odds of trying to quit drinking (OR 1.77; $p = 0.007$) and being careful about situations for drinking (OR 1.66; $p = 0.029$) (Bernstein et al., 2010). However, there were no significant between group differences for actual alcohol consumption measured as drinking days/month, mean drinks/drinking day, mean drinks/week and maximum drinks/day. Graduate students providing BMI to those convicted of driving under the influence of alcohol, led to a significant reduction in MCV (9.6 fL vs. 1.75 fL, $p < 0.005$), compared to controls (Brown et

al., 2010). In a study with Hispanic participants, compared to TAU, BMI provided by NSHWs in an urban trauma centre also led to significantly greater reduction in drinks/week (Effect size $d=0.14$, $p=0.01$), maximum amount consumed (Effect size $d=0.30$, $p=0.02$), and percentage days heavy drinking (Effect size $d=0.24$, $p=0.02$). In the same study, although there was a reduction in drinking in White and Black participants as well, BMI did not significantly differ from TAU (Field et al., 2010). MET provided to hazardous drinkers by primary care nurses led to a significant ($p<0.05$) reduction in average drinking per drinking day (2.26 drinks/day vs. 4.02 drinks/day) and average drinks per week (4.72 drinks/week vs. 11.24 drinks/week) (Noknoy et al., 2010). Finally, in one RCT, BI provided by occupational health nurses in the workplace was not significantly different from control in reducing AUDIT scores (Hermansson et al., 2010).

Only one study fulfilled all criteria relevant to PREMIUM i.e. LMIC, primary care setting and intervention provided by NSHW (Noknoy et al., 2010). In this study, compared to assessment only, MET delivered to hazardous drinkers by nurses in primary care led to significantly better drinking outcomes.

Table 2.4: Effectiveness of psychosocial interventions for alcohol use disorders

Author (Year), Country	Effect Size/Description of results
BRIEF INTERVENTIONS	
Carroll et al (2009), USA	d=0.17
Roudsari et al (2009), USA	At one year there was no association between BI and the 3 outcomes.
Tsai et al (2009), Taiwan	At 6 months there was no significant in difference in mean AUDIT scores between groups At 12 months there was a significant difference in mean AUDIT scores between UC and BI (55.1% vs. 45.3%, p<0.05)
Bager et al (2010), Denmark	68% abstinent in BMI compared to 40% in UC; p< 0.05
Baker et al (2010), Australia	Men reduced their drinking more if they received alcohol-focused intervention while women reduced their drinking more if they received the depression-focused intervention. Integrated intervention resulted in a greater reduction in drinking days than single-focused interventions. Greater reduction in alcohol consumption after 10 sessions of intervention than BI
Bernstein et al (2010), USA	BMI was superior to control on the following outcomes: <ul style="list-style-type: none"> • Attempt to quit drinking: OR 1.77; p=0.007 • Careful about situations for drinking: OR 1.66; p=0.029
Brown et al (2010), Canada	Significant group difference in change on MCV from T0, with BMI producing greater reductions compared to control at T1 but not at T2
Field et al (2010), USA	Effect sizes in Hispanics:

Author (Year), Country	Effect Size/Description of results
	<ul style="list-style-type: none"> • Average number of standard drinks consumed per week- $d = 0.14$ • Maximum amount consumed at 6-month follow-up- $d = 0.29$ • Maximum amount consumed at 12-month follow-up- $d = 0.30$ • Percentage days heavy drinking at 6-month follow-up- $d = 0.26$ • Percentage days heavy drinking at 12-month follow-up- $d = 0.24$
Hermansson et al (2010), Sweden	There were no statistically significant differences between the two intervention groups and the control group with respect to the AUDIT or CDT results
Noknoy et al (2010), Thailand	<p>Average drinking per drinking day during the previous week significantly ($p < 0.05$) lower at 6 weeks, 3 and 6 months.</p> <p>Hazardous drinking per drinking day during the previous week, average drinking per week during the previous week, hazardous drinking per week during the previous week significantly ($p < 0.05$) lower at 3 and 6 months</p>
Gwaltney et al (2011), USA	At 6 months post intervention, compared to MI, FO was significantly associated with an increased likelihood of heavy drinking, $OR = 1.72$ (95% $CI = 1.15 - 2.56$, $p < 0.0001$).
Liu et al (2011), Taiwan	Significant 12-month intervention effect among unhealthy drinkers, with the BI having greater improvements.

Author (Year), Country	Effect Size/Description of results
OTHER INTERVENTIONS	
Fals-Stewart et al (2009), USA	<p>Among gay couples the percentage days heavy drinking changed from 41.94% at baseline to 18.00% at follow up in BCT and from 43.84% to 32.16% in IBT.</p> <p>Among lesbian couples percentage days heavy drinking changed from 38.62% at baseline to 15.71% at follow up in BCT and from 39.8% to 27.92% in IBT.</p> <p>BCT had significantly different scores than those in IBT at the assessment period based on pairwise contrasts ($p < .05$).</p>
Kavanagh (2009), Australia	<p>Among men the mean weekly alcohol consumption in the immediate correspondence arm reduced from 62.2 units/week at baseline to 33.7 units/week at 3 months and in the delayed correspondence arm it reduced from 66.1 units/week to 51.4 units/week.</p> <p>Among women the mean weekly alcohol consumption in the immediate correspondence arm reduced from 40.8 units/week at baseline to 24.4 units/week at 3 months and in the delayed correspondence arm it reduced from 40.7 units/week to 29.3 units/week.</p> <p>Immediate correspondence had a greater reduction than delayed correspondence ($p = 0.006$)</p>
Sobell et al (2009), Canada	Significant reduction in SD in both groups but no between group differences
Barrowclough et al (2010), UK	OR of intervention group participant being in one of the more abstinent groups versus one of the less

Author (Year), Country	Effect Size/Description of results
	abstinent groups 1.50 (95% CI 1.08 to 2.09; p=0.016)
Gregory et al (2010), USA	Cohen's d=0.39
Witkiewitz et al (2010), USA	No statistically significant difference between MBRP and TAU

A meta-analysis was not conducted because of the heterogeneity of the interventions and the outcomes measured in the various RCTs.

2.3.10 Supplementary evidence from systematic reviews

6 systematic reviews (Kaner et al., 2011; Kaner et al., 2009; Magill and Ray, 2009; Moreira et al., 2009; Riper et al., 2009; Webb et al., 2009) were identified as supplementary evidence

These included two systematic reviews of BIs (Kaner et al., 2011; Kaner et al., 2009) and one each of CBT (Magill and Ray, 2009), personalised feedback (Riper et al., 2009), social norms interventions (Moreira et al., 2009), and workplace based interventions (Webb et al., 2009) (comprising a mixture of a range of psychosocial interventions). Details of the systematic reviews are described in Table 2.5.

Table 2.5: Effectiveness of psychosocial interventions for alcohol use disorders (Systematic reviews)

Author (Year)	Intervention	Number of studies	Type of studies	Population
Moreira et al (2009)	Social norms intervention	22	RCT	University or college students
Kaner et al (2009)	BI	Review 29 Meta-analyses 25	RCT	<p>Inclusion criteria in terms of alcohol consumption varied (Number of standard drink units per week, a screening tool score, or evidence of binge drinking)</p> <p>Patients were usually excluded if they were severely alcohol dependent or already on an alcohol intervention programme.</p>
Magill et al (2009)	CBT	53	RCT	Alcohol abuse or dependence
Riper et al (2009)	Personalised feedback	14	RCT	<ul style="list-style-type: none"> ▪ Binge drinking ▪ Drinking in excess of a low-risk drinking guideline ▪ Amount of alcohol intake (40 oz. ethanol in the past month and 40 standard drinks in the past month)

Author (Year)	Intervention	Number of studies	Type of studies	Population
Webb et al (2009)	Workplace based interventions	10	RCT Randomized trials with no controls Time series evaluation Non randomized trials	The target populations included work places in the manufacturing sector, in the service industries of mail delivery, printing and civic services and one in the health-care industry, white- and blue-collar workers; some did not specify type of worker. The workplaces were all large-scale, with only one having fewer than 1000 employees
Kaner et al (2011)	BI	14	RCT Quasi experimental pilot study	AUD

In the systematic review of BI (Kaner et al., 2009), at 1 year, participants receiving BI drank less alcohol per week than those receiving a control intervention (weighted mean difference = -38 g, 95%CI: -54 to -23 g/week). This benefit of BI was seen in both effectiveness (weighted mean difference = -33 g, 95%CI: -51 to -16 g/week) and efficacy trials (weighted mean difference = -45 g, 95%CI: -70 to -19 g/week). Meta-analysis restricted to the 10 trials that confirmed concealment of allocation to intervention group and the four cluster randomised trials showed similar positive results in favour of BI. In the other systematic review of 14 RCTs testing BI in substance use comorbid with physical or mental health conditions, only two RCTs were specific for AUDs (Kaner et al., 2011). These studies reported significantly higher abstinence rates and drop in weekly drinking in the intervention group compared to controls. A systematic review of CBT for AUD revealed a small pooled standardised mean difference (SMD) ($g=0.144$; 95% CI 0.094- 0.194, $p < 0.005$) (Magill and Ray, 2009). In a meta-analysis of personalised feedback the pooled standardized-effect size for reducing alcohol consumption was modest ($d=0.22$, 95% CI 0.16-0.29) (Riper et al., 2009). In the systematic review of social norms interventions in college and university students there was a significant effect of individual face to face feedback (IFF) on drinking frequency (SMD -0.39 95% CI -0.66 to -0.12), and binge drinking (SMD -0.25 95% CI -0.49 to -0.02); and of group face to face feedback (GFF) on drinking quantity (SMD -0.32 95% CI -0.63 to -0.02) and binge drinking (SMD -0.38 95% CI -0.62 to -0.14) (Moreira et al., 2009). In the systematic review of interventions in the workplace brief interventions, interventions contained within health and life-style checks, psychosocial skills training and peer referral were reported to have potential to produce beneficial results on drinking outcomes (Webb et al., 2009).

To summarise, the systematic reviews provided aggregate evidence of effectiveness for BI, CBT and personalised feedback (including social norms intervention) in the management of AUD.

2.4 Output

This review was conducted to update the evidence base that informed the mhGAP-IG (WHO, 2010b). The mhGAP recommends the use of the following psychosocial interventions for AUD: BI for harmful drinking and self help groups like AA for alcohol dependence. The psychosocial strategies recommended for

BI in the mhGAP-IG include behavioural strategies (e.g. not having alcohol at home, not going to pubs or other locations where people use alcohol); family involvement; and MI (e.g. discussing pros and cons of drinking, rolling with resistance, promoting independence). Our review adds further evidence in support of these strategies and also provides evidence for additional strategies as shown in Table 2.6.

This systematic review reiterates that BI based on a range of strategies, including the most commonly used MI, are effective in reducing alcohol consumption. This systematic review also found evidence that other interventions based on cognitive and/or behavioural principles and alternative delivery methods (postal and telephone) were effective in reducing alcohol consumption in AUDs. With regard to relevance of the evidence to the PREMIUM context, there was some evidence supporting interventions for AUD being effective in LMIC/ethnic minorities, when delivered in primary care, and when delivered by NSHW. One RCT of MET from a LMIC (Thailand) was effective in reducing alcohol consumption in hazardous drinkers. One RCT of BMI in a mixed ethnic sample in the USA reported a differential effectiveness in reducing alcohol consumption based on ethnic subgroup i.e. effective in Hispanics but not in Whites or Blacks. A range of BIs and correspondence treatment (based on principles of CBT) provided in primary care are effective in reducing alcohol consumption. Finally, a range of BIs provided by NSHWs in both primary care and non-mental health secondary care settings were effective in reducing alcohol consumption.

Thus this systematic review and the mhGAP-IG generated a list of effective psychosocial interventions for AUD and we used the following criteria to rate the strength of the evidence of effectiveness of the interventions and generalisability of the evidence to the PREMIUM programme settings.

Table 2.6: Scoring metric to decide eligibility for PREMIUM based on effectiveness and generalisability

Evidence for Effectiveness	Rating	Generalisability for PREMIUM
		(1 point for each criteria)

Systematic review	+++	Evidence from LMIC
		Evidence in PHC setting
More than one RCT	++	Evidence of delivery by NSHWs
One RCT	+	Evidence in a sample of ethnic minority/disadvantaged.
Not effective	-	

Table 2.7 shows the application of this scoring scheme to the psychosocial interventions derived from this systematic review.

Table 2.7: Scoring of the psychosocial interventions on effectiveness and generalisability parameters

		Generalisability				
Psychosocial intervention	Effectiveness	LMIC	Primary Care setting	Disadvantaged or Minority population	NSHW delivered	Total
Brief Interventions based on MI	+++	✓	✓	✓	✓	4
Behavioural couples therapy (BCT) plus individual-based treatment (IBT)	+					0
Immediate Correspondence Treatment	+		✓			1
Individual Guided Self Change (GSC)	-					0

		Generalisability				
Psychosocial intervention	Effectiveness	LMIC	Primary Care setting	Disadvantaged or Minority population	NSHW delivered	Total
Dynamic Deconstructive Psychotherapy (DDP)	+					0
Mindfulness Based Relapse Prevention (MBRP)	-					0
CBT	+++					0
Social Norms intervention	+++					0
Personalised feedback	+++					0

Psychosocial interventions that met the following criteria were then selected for further consideration in the psychosocial intervention development process:

- 1) Any psychosocial intervention with effectiveness evidence of +++ irrespective of generalisability score;
- 2) Any psychosocial intervention with effectiveness evidence of ++ if generalisability score was at least 1; and
- 3) Any psychosocial intervention with generalisability of 2+ even if effectiveness was only +

These parameters were developed and key decisions on selection of psychosocial intervention strategies were carried out in consultation with members of PREMIUM's Investigator Group, which was made up of national and international experts on AUD and psychosocial intervention development.

Thus, the evidence based psychosocial interventions for AUD selected from the international literature were:

1. MI,
2. Cognitive and/or Behaviour Therapy,
3. Personalised feedback, and
4. Social norms intervention.

The former two were also psychosocial interventions recommended in the mhGAP-IG. We then proceeded to dismantle these PTs into their active strategies to move to the next stage of intervention development. The strategies that we derived from these four psychosocial interventions included the following: MI, personalised feedback, and cognitive restructuring (Table 2.8).

Table 2.8: Psychosocial intervention strategies selected for next stage of intervention development

INTERVENTION STRATEGY	SOURCE	
	mhGAP	INTERNATIONAL LITERATURE REVIEW
Personalised feedback		✓
Motivational interviewing	✓	✓
Cognitive restructuring	✓	✓

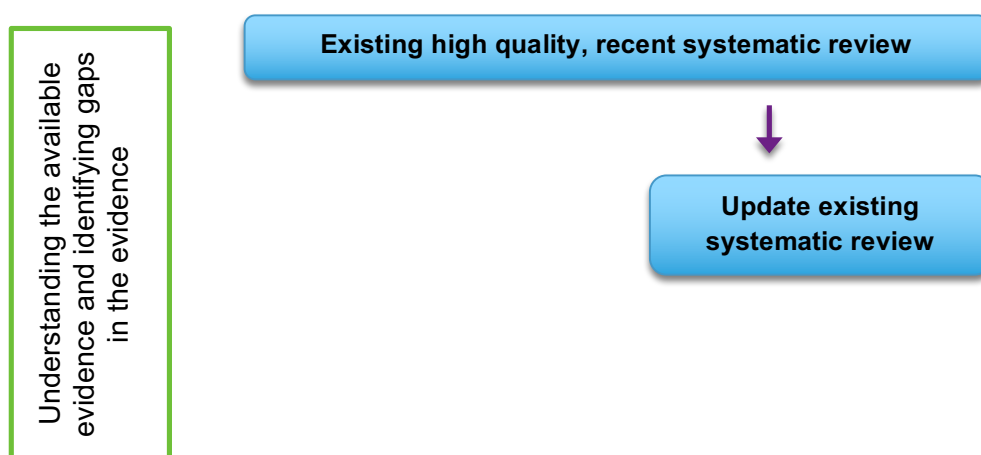
These strategies progressed to the next step of the intervention development process where they were supplemented/supported by local and contextualised evidence. In the next chapter I will describe the literature review conducted to synthesise local evidence of psychosocial interventions for AUD.

Chapter 3 Literature Review of Psychosocial Interventions for Alcohol Use Disorders in India[†]

3.1 Background

The systematic review of psychosocial interventions for harmful drinking described in Chapter 2 aimed at updating the evidence base synthesized by the Mental Health Gap Action Programme (mhGAP) (Figure 3.1). In this update the focus was on identifying the highest quality of evidence (i.e. Randomised Controlled Trials and Systematic Reviews) published in indexed peer reviewed journals. However, this effectively meant that any evidence that is published in non-indexed journals, studies that were not Randomised Controlled Trials (RCT), and grey literature from India, the contextually relevant setting for PREMIUM, was not represented in the systematic review.

Figure 3.1: Progress of the intervention development process



Thus, the non-inclusion of such contextual literature was a limitation of the systematic review described in Chapter 2. However, such a gap in the synthesis of evidence was inconsistent with the aim of the intervention development process in PREMIUM, which was to take into consideration contextual and cultural factors affecting intervention feasibility, acceptability, and effectiveness. Hence another review was conducted with the aim to review the range of psychosocial interventions for Alcohol Use Disorders (AUD) in India and to examine them for evidence of effect and relevance to PREMIUM's context.

[†]Author contribution to the methods: I analysed the data, synthesised the results, and interpreted the findings.

3.2 Methods

3.2.1 Search strategy

The following strategies were used to identify the literature covering the period from 1st January 1990 to 31st March 2011. The lower end of the cut off date was selected for reasons of convenience and to identify only contemporary interventions for AUD.

- a) Electronic database search: The following databases were used for the search-Medline, PsycInfo, PsycExtra and IndMed (electronic database indexing papers published in Indian biomedical journals). For Medline, PsycInfo, and PsycExtra the following search terms were used: (alcohol* OR drinking OR addiction) AND India AND psycho* OR therapy OR counseling OR counselling OR behavior OR behaviour OR intervention OR harm reduction) NOT (pharma* OR medic*). For IndMed the same search terms were used except 'India' as by default the database would search only for Indian publications.
- b) The reference lists of papers selected for the review were hand searched for additional eligible papers.
- c) Key informants in the region were contacted to recommend any relevant articles that the electronic database search might have missed. The key informants (Appendix 1) were mainly psychosocial intervention experts and mental health professionals from various parts of India, and they were contacted by email and/or phone to obtain a list of relevant literature. Additional key informants were also identified through snowballing.
- d) Key local libraries (Appendix 2) were visited for the following: i) hand search of the table of contents of non-indexed journals; and ii) search of library catalogues for eligible project reports, manuals and dissertations. Where electronic catalogues were available in the libraries, the search terms employed for electronic database searches were used.

3.2.2 Data screening

The titles of the papers identified through the various search strategies were

screened and the abstracts of potentially eligible papers were retrieved. These abstracts were then examined for possible inclusion and full texts of selected papers were retrieved. These full texts were then examined to determine their compliance with eligibility criteria described below and summarized in Table 3.1.

3.2.3 Eligibility criteria

Since the published literature on evidence based psychosocial interventions for AUD in India is sparse, the eligibility criteria were devised to cast a wider net compared to the international literature review. Thus the threshold for inclusion into this review was intentionally kept lower as compared to the systematic review described in Chapter 2, as the aim was to identify all contextualised evidence. This included RCTs, observational studies (surveys, case control studies, cohort studies, case series), and pilot studies. Only papers published in the English language were selected as all academic publications in India are in the English language. Only studies conducted in adults (19 years and above) were included as the intervention being developed was for adults. Studies conducted in exclusively female samples were excluded as the intervention was being developed only for males.

Although the intervention being developed was for harmful drinking, studies in any type of AUD were included, as research evidence on psychosocial interventions for AUD in India is sparse to start with and a narrow eligibility criterion would have led to a poor yield of contextualised evidence. Studies testing psychosocial interventions by themselves or in combination with a pharmacological intervention were included. However, studies testing purely pharmacological interventions were excluded for obvious reasons. Studies testing psychosocial interventions delivered on a computer or internet-based interventions were excluded as the aim of PREMIUM was to develop an intervention which could be delivered by a non specialist health worker and hence technology driven interventions were not relevant to this project.

Table 3.1: Eligibility criteria for the literature review

	Inclusion criteria	Exclusion criteria
Type of study	<ul style="list-style-type: none"> • RCT. • Any observational study. • Pilot studies. • Case series. 	<ul style="list-style-type: none"> • Case reports.
Publication language	English language.	
Participants	<ul style="list-style-type: none"> • Adults (19 years and above). 	<ul style="list-style-type: none"> • Children and adolescents. • Exclusively female samples.
Disorder	<ul style="list-style-type: none"> • Any type of AUD. • AUD comorbid with any other substance use disorder or mental or physical disorder provided the AUD was the primary focus of treatment. 	
Intervention	<ul style="list-style-type: none"> • Psychosocial intervention. • Psychosocial intervention combined with pharmacological intervention. 	<ul style="list-style-type: none"> • Purely pharmacological intervention. • Computer/internet based interventions.
Comparison group	<ul style="list-style-type: none"> • Treatment as usual. • No treatment. • Enhanced usual care. 	

	Inclusion criteria	Exclusion criteria
	<ul style="list-style-type: none"> • Another psychosocial intervention. • Pharmacological treatment. 	

3.2.4 Data extraction and analysis

The data from included papers were extracted into an a priori designed structured data extraction sheets. The studies were examined with regards to evidence of effectiveness/impact. Data was collected about the study setting, sample, type of intervention with details of content and delivery procedures, therapist qualifications, control group (if any) and results of the evaluation of the intervention.

The quality of each RCT was assessed for adequacy of randomization, blinding and attrition using the Jadad criteria (Jadad et al., 1996). The total Jadad score can range from 0 to 5. One point is given for each of the following criteria:

1. Study described as randomised,
2. Method of randomisation was appropriate,
3. Study described as double blind,
4. Method of double blinding was appropriate, and
5. Description of withdrawals/drop outs was provided.

One point is deducted if the method of randomisation was inappropriate or the method for double blinding was inappropriate.

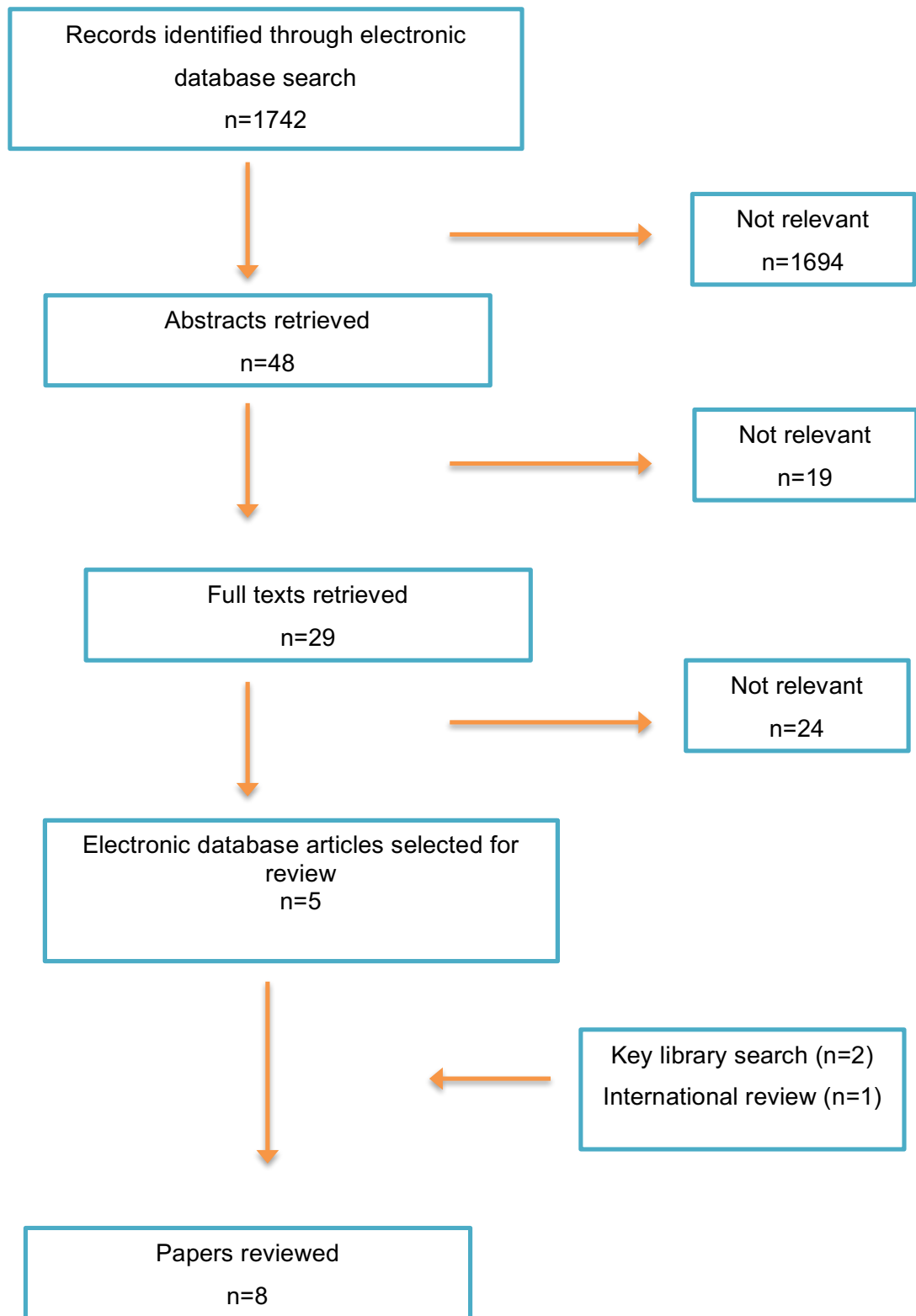
The selection of papers, data extraction and quality assessment were conducted by one reviewer and consultation sought when necessary with another reviewer who was blind to the findings of the first reviewer. The data was analysed qualitatively as there was extensive heterogeneity in study design, sample description and outcomes measured.

3.3 Results

The database search identified 1742 articles, and through a process of sequential screening, five articles were selected for inclusion in the review (Chavan et al., 2003; Khalsa et al., 2008; Kumar and Thomas, 2007; Kuruvilla, 2004; Pal et al., 2007) (Figure 3.2). The reasons for exclusion of the papers included the following: substances of abuse was not alcohol (n=487), papers describing epidemiological data about AUD and not evaluation of intervention

(n=668) and papers describing intervention for disorders other than substance use disorders (n=539). Two additional articles were retrieved through the library search (Narvekar, 2003; Ramesh and Kumaraiah, 1997). One paper reporting the findings of an RCT from India identified through the international review (Chapter 2) was included in this review (Nattala et al., 2010)

Figure 3.2: Flow diagram of studies included in the systematic review from India



3.3.1 Brief Interventions (BI) based on Motivational Interviewing (MI)

MI based BIs were described in one Non Randomized Trial (NRT) and one case series.

The NRT was conducted in an urban setting with 90 men (20-45 years) with 'harmful drinking' (defined as a score of 8 to 24 on the Alcohol Use Disorders Identification Test [AUDIT]) (Pal et al., 2007). Patients were alternately allocated to BI and simple advice arms. An experienced mental health specialist delivered BI in two sessions of 45 minutes each separated by 3-5 days. The strategies implemented in BI were personalised feedback, psycho-education and MI. The participants in the control arm received five minutes of simple advice (SA) where the counsellor expressed concern about the consequences of the participants' alcohol consumption and advised them to cut down alcohol use. Compared to SA, BI led to a significant change in the Addiction Severity Index (ASI) score. At six months follow up, in the BI group the mean (SD) ASI score reduced from 24.71 (8.37) at baseline to 10.07 (9.81) and in the SA group it reduced from 26.07 (6.47) at baseline to 19.05 (10.63) and the change was statistically significant ($p < 0.001$).

In the case series, trained nurses delivered the BI to 42 men with hazardous drinking in primary care setting in Goa (Narvekar, 2003). The intervention comprised of screening, personalised feedback, MI and psycho-education. In this study there was a statistically significant reduction in post intervention AUDIT scores ($p = 0.001$).

3.3.2 Family Therapy

One RCT and one NRT each tested the effectiveness of family therapy in the treatment of AUD.

In the RCT, 30 patients with alcohol dependence admitted to a tertiary care de-addiction unit were randomly assigned to individual relapse prevention (IRP), dyadic relapse prevention (DRP), and treatment as usual (TAU) groups (Nattala et al., 2010). In IRP, the intervention was administered to the individual participant while in DRP, both the participant and a family member received the intervention. IRP comprised of counselling the individual about relapse prevention strategies and DRP consisted of family counselling and family

psycho-education in addition to the relapse prevention strategies used in IRP. TAU consisted of long-term medication to deal with craving, and psychosocial intervention involving education about the likely harms from alcohol and advice about quitting, managing triggers for drinking, practising drink refusal skills, and making positive lifestyle changes. A trained psychiatric nurse delivered the interventions. DRP was significantly ($p<0.05$) better than TAU and IRP in reducing alcohol consumption at the end of six months. DRP was significantly ($p<0.05$) better than IRP and TAU in reducing the mean number of family problems, and DRP was significantly ($p<0.05$) better than TAU in reducing the mean number of occupational problems and financial problems. IRP was not significantly superior to TAU on any of the outcome measures. The RCT scored one point on the Jadad quality rating for being described as randomised.

The NRT conducted in a mental health specialist unit compared the effectiveness of family therapy with brief problem focused supportive psychotherapy (Kumar and Thomas, 2007). The participants were recruited after detoxification and consisted of 35 participants each in the intervention and control groups. The intervention strategies used in family therapy were family psycho-education, involvement of family member and addressing interpersonal issues with one's partner. The intervention was delivered in 10 to 20 sessions of 45 minutes each on a monthly basis. Compared to the control, family therapy led to a significant reduction in alcohol intake viz mean Michigan Alcohol Screening Test (MAST) reduced significantly ($p<0.01$) in the intervention arm compared to control arm at 6 months and also at 12 months.

3.3.3 Twelve Step Facilitation (TSF) based on Alcoholic Anonymous (AA)

A case series was conducted to test a TSF intervention based on AA in a mental health specialty setting with men having alcohol dependence (Kuruvilla, 2004). The intervention was delivered to 187 patients, by non-specialist health workers (NSHW), over two to three weeks in a residential setting. The strategies used in the intervention comprised use of support groups, addressing religious and spiritual issues and befriending. Post intervention follow up services were provided in some of the communities where functional AA groups were available. The follow up services comprised of encouraging patients to attend AA meetings in the locality and, as and when required, home visits by

AA members. 33.3% of the sample reported being sober at the end of one year and the presence of a follow up worker in the community improved the sobriety rates ($p=0.04$).

3.3.4 Behavioural Therapy (BT)

A case series evaluating effectiveness of BT in 20 patients with alcohol dependence was conducted in a mental health specialist care setting (Ramesh and Kumaraiah, 1997). A trained mental health specialist delivered the intervention over a period of 45 days in daily one-hour sessions. The intervention strategies used in BT were social skills training, relapse prevention and family counselling using BT principles. 16 months after completion of the intervention there was a significant reduction in alcohol consumption measured on the short form of Short Alcohol Dependence Data (SADD) questionnaire ($p<0.001$).

3.3.5 Religious and spiritual strategies

A case series with 10 patients of alcohol dependence evaluated the use of Kundalini Yoga (regular practice of meditation, pranayama, chanting mantra and yoga asana) in a mental health specialty residential setting (Khalsa et al., 2008). Kundalini Yoga was delivered by certified Kundalini Yoga therapists over 90 days and the intervention strategies comprised of psycho-education, relapse prevention and addressing religious and spiritual issues through Yoga. At one-month post intervention there was significant reduction in scores on Behaviour and Symptom Identification Scale (BASIS-32) measuring self reported symptoms (e.g. depression and anxiety, daily living and role functioning) ($p<0.05$) and a significant positive change on the Quality of Recovery Index (QRI) ($p<0.005$) which measures change in substance related behaviour.

3.3.6 'Complex Intervention'

A NRT evaluated the effectiveness of a 'complex intervention' for alcohol dependence in two different settings; namely community setting ('camp approach') in intervention group ($n=67$) and hospital setting in control group ($n=44$) (Chavan et al., 2003). The strategies used in the intervention, included psycho-education, family counselling, addressing religious and spiritual issues

and relapse prevention. A team consisting of a psychiatrist and a psychiatric social worker delivered the intervention in the control group. In the intervention arm, in addition to the psychiatrist and a psychiatric social worker, a village health worker helped the intervention team in identification and referral of patients to the intervention. At three months post discharge, there was no significant difference between the two groups in terms of abstinence ($p=0.055$).

Tables 3.2 and 3.3 describe the studies included in this review. For each of the studies included in this review I examined the papers for the description of the psychosocial intervention tested in that particular study. Wherever described, I extracted the psychosocial strategies that were delivered as a part of that particular psychosocial intervention (Table 3.4).

Table 3.2: Non RCTs of psychosocial interventions for AUD from India

Author, Year	Setting	Sample	Intervention	Intervention details	Therapist	Control	Results
Kumar, 2007	Tertiary care	35 men with alcohol dependence in each arm	Family therapy	10 to 20 sessions of 45 minutes each on monthly basis	Multi disciplinary team of psychiatrist, and social worker	Brief problem focused supportive psychotherapy	Significant reduction of MAST score in family therapy arm
Pal, 2007	Community	Males between 20-45 years; AUDIT score 8- 24; 45 in each arm	BI	Two 45 minute sessions of MI	Mental health specialist	Simple advice for 5 minutes	Significant interaction between the intervention and change in ASI alcohol use in past 30 days (p=0.001)
Chavan, 2003	Community	Males with alcohol	'Complex intervention'	10 days residential,	Multidisciplinary team of	Same as intervention arm	No significant difference in both groups at time of

Author, Year	Setting	Sample	Intervention	Intervention details	Therapist	Control	Results
		dependence, 67 in intervention arm and 44 control arm	using 'Camp approach'	psycho-education, recreational activities, religious strategies involving both patient and family, Yoga, and relapse prevention	psychiatrist, social worker, village volunteer	but delivered over 30 days in closed wards	discharge and at 3 month after discharge

Table 3.3: Case series of psychosocial interventions for AUD from India

Author, year	Setting	Sample	Intervention	Intervention details	Therapist	Results
Khalsa, 2008	Specialist mental healthcare	10 patients with substance abuse	Kundalini yoga	90 days residential programme of Kundalini Yoga	Kundalini Yoga certified teacher	Significant reduction in post test scores on BASIS- 32 and QRI ($p<0.005$)
Kuruvilla, 2004	Specialist mental healthcare setting	187 men with alcohol dependence	TSF	Residential AA based intervention for 2-3 weeks and monthly follow up	AA workers	33.4% participants sober at one year
Narvekar 2003	Primary care	42 men with hazardous drinking	BI	1-3 sessions of MI, information booklet	Staff nurse	Significant reduction in post test AUDIT scores ($p=0.001$)

Author, year	Setting	Sample	Intervention	Intervention details	Therapist	Results
Ramesh, 1997	Specialist mental healthcare setting	20 male patients with alcohol dependence	BT	Social skills training with behavioural counselling 1 hour daily for 30 days	Mental health counsellor	Significant reduction in SADD score at 16 months follow up ($p<0.001$).

3.4 Output

Except for one RCT (Nattala et al., 2010), the studies that tested these psychosocial strategies did not have study designs that met the stringent criteria set for selection in the international literature review described in Chapter 2. Except for one intervention delivered by AA members and one delivered in primary care all the other interventions were either delivered by specialists and/or were delivered in secondary/tertiary care settings. However these studies were selected because they tested psychosocial interventions for AUD in Indian settings and hence were contextually relevant to the PREMIUM project.

Thus the output of this step of the intervention development process was a list of psychosocial strategies for AUD that had been tested and had shown statistically significant impact/effectiveness in contextually relevant settings. These were contextually relevant by virtue of being used in Indian settings. However they were further examined on two other criteria relevant to the PREMIUM context i.e. delivery by NSHW and delivery in primary care (Table 3.4). None of the psychosocial strategies ticked the boxes for both these criteria. However three each met either of those criteria. In the studies included in this review, personalised feedback, MI and psycho-education were delivered in primary care, while addressing religious and spiritual issues, support groups, and befriending were delivered by NSHW.

Table 3.4: Strategies from the research studies with statistically significant findings included in the review

Psychosocial intervention strategy	Relevance to PREMIUM		Author, Year
	NSHW	Primary care	
Kundalini yoga			Khalsa, 2008
Family counselling			Kumar, 2007; Nattala, 2010; Ramesh, 1997
Family psycho education			Nattala, 2010
Addressing interpersonal issues with one's partner			Kumar, 2007
Personalised feedback		✓	Narvekar, 2003
MI		✓	Pal, 2007; Narvekar 2003
Psycho-education		✓	Narvekar, 2003
Addressing religious and spiritual issues	✓		Kuruvilla, 2004
Support group (Twelve Step Facilitation)	✓		Kuruvilla, 2004
Befriending	✓		Kuruvilla, 2004

Psychosocial intervention strategy	Relevance to PREMIUM		Author, Year
	NSHW	Primary care	
Relapse prevention			Nattala, 2010; Ramesh, 1997
Social skills training			Ramesh, 1997

Thus, the psychosocial strategies derived from this review of evidence which then moved to the next stage of the intervention development process included psycho-education, support groups, relapse prevention, social skills training, family psycho-education, family counselling, religious and spiritual practices, Kundalini Yoga, addressing interpersonal issues with one's partner and befriending. Besides these psychosocial strategies, this review also provided contextually relevant (i.e. based in India) evidence for personalised feedback and MI, strategies that were also supported by evidence from the international review. Table 3.5 lists the various strategies that moved to the next step of the intervention development process and the sources from which these strategies were derived.

Table 3.5: Psychosocial intervention strategies selected for next stage of intervention development

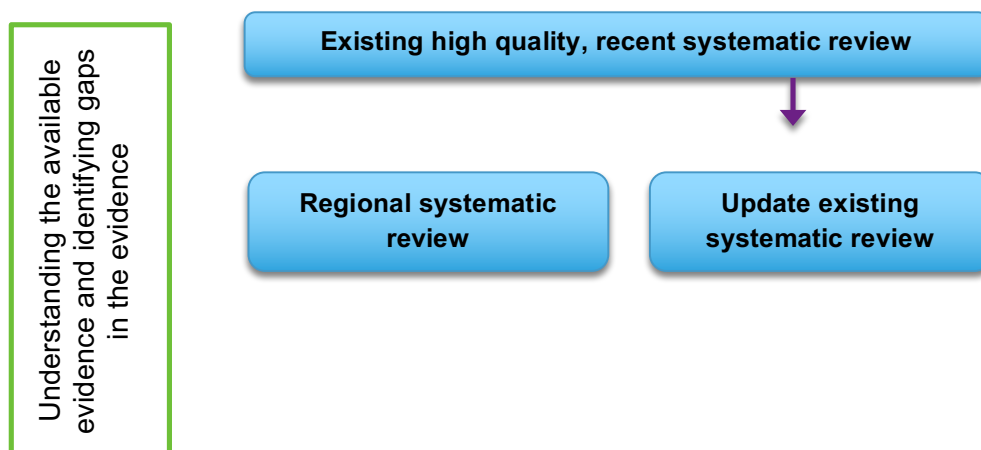
INTERVENTION STRATEGY	SOURCE		
	mhGAP	LITERATURE REVIEW	
		International	Indian
Personalised feedback		✓	✓
Motivational interviewing	✓	✓	✓
Cognitive restructuring	✓	✓	
Psycho-education			✓
Support groups			✓
Relapse prevention			✓
Social skills training			✓
Family psycho-education			✓
Family counselling			✓
Religious and spiritual practises			✓
Kundalini Yoga			✓
Addressing interpersonal issues with one's partner			✓
Befriending			✓

Chapter 4 Literature Review of Explanatory Models of Alcohol Use Disorders in South Asia[§]

4.1 Background

In Chapters 2 and 3 I examined the global and local evidence on effectiveness/impact of psychosocial treatments for Alcohol Use Disorders (AUD) (Figure 4.1). This was done with the goal of identifying best available global evidence through the international review and best available local evidence from India. Taking this approach of understanding context to inform culturally appropriate interventions a step further, in this chapter and the next we explore explanatory models of AUD in South Asia and India respectively. In doing so we attempt to bring about a convergence of the ‘etic’ and ‘emic’ approaches to develop an intervention which is informed by the best available scientific evidence and integrate it with local schema.

Figure 4.1: Progress of the intervention development process



After having examined the ‘etic’ (“accounts, descriptions, and analyses expressed in terms of the conceptual schemes and categories regarded as meaningful and appropriate by the community of scientific observers”) (Lett, 1990) in the reviews of the biomedical literature in Chapters 2 and 3, in this chapter and the next I will explore the ‘emic’ (“accounts, descriptions, and analyses expressed in terms of the conceptual schemes and categories regarded as meaningful and appropriate by the native members of the culture whose beliefs and behaviours are being studied”) (Lett, 1990) with the eventual goal of using this to inform an intervention which is potentially effective (as it is

[§] Author contribution to the methods: I analysed the data, synthesised the results, and interpreted the findings.

based on robust scientific evidence) and acceptable to the recipients (as it is informed by local explanatory models). Explanatory models are the belief systems that people have about what has caused their illness and what the illness does to them (Weiss, 1997). These are further described as the “notions about an episode of sickness and its treatment that are employed by all those engaged in the clinical process” (Kleinman, 1980). It is important to take into account such explanatory models while designing culturally relevant psychosocial interventions as such beliefs and behaviours do influence help seeking behaviour, acceptability of the intervention, subsequent concordance and eventual patient satisfaction. According to Aisenberg, a literal translation of a manualised protocol of an existing evidence based psychosocial intervention is not adequate and adaptation must also address context by incorporating relevant metaphors, cultural values, customs, and traditions into the intervention (Aisenberg, 2008). Explanatory models contribute to the conceptualization of an illness by the community and affected persons, and a clear understanding of these explanatory models help in improving intervention content, acceptability and effectiveness. In PREMIUM, the explanatory models were explored in two ways, through a review of explanatory models in South Asia (described in this chapter) and through a qualitative study of explanatory models in India (described in Chapter 5).

The aim of this review is to describe the explanatory models of AUD in South Asia to understand the conceptualization of causes of AUD, and the help-seeking behaviour of patients with AUD.

4.2 Methods

4.2.1 Search strategy

The following three sources were searched for relevant literature:

i) Electronic database search

a) Medline, PsycInfo and PsycExtra were searched using the following search terms: (alcohol* OR drinking OR addiction) AND (South Asia OR India OR Pakistan OR Bangladesh OR Sri Lanka OR Bhutan OR Nepal

OR Maldives OR Afghanistan) AND (help seeking OR coping OR self help OR explanatory model OR illness narrative).

b) IndMed, a database of Indian biomedical journals, was searched using the following search terms: (alcohol* OR drinking OR addiction) AND (help seeking OR coping OR self-help OR explanatory model OR illness narrative).

ii) Papers identified through the literature search of local evidence for psychosocial interventions for AUD (Chapter 3) were screened to identify any papers relevant for this review.

iii) Grey literature was searched in the same manner as for the review of psychosocial interventions for AUD in India. For details refer to section 3.2.1 in Chapter 3. Details of key local libraries and key informants that were accessed are provided in Appendices 1 and 2.

4.2.2 Eligibility criteria

The inclusion and exclusion criteria for this review (Table 4.1) were as follows: All literature describing explanatory models of and coping strategies in AUD from South Asia was included. We included all types of study designs. Only publications in English were included. Studies in adults (19 years and above) of any gender were included. Only studies in adults were included as the intervention being developed was for adults. Any gender was included, as we wanted to include explanatory models and coping strategies of men with AUD as well as their family members (who could be women). Studies of participants with any type of AUD were included. Studies in patients with AUD comorbid with physical illness were included. Studies in patients with AUD comorbid with other psychiatric conditions or other substance use disorder as the primary diagnosis were excluded as the explanatory models of such conditions were expected to differ from those having only AUD.

Table 4.1: Eligibility criteria for the literature review of explanatory models in South Asia

	Inclusion criteria	Exclusion criteria
Type of study	Any study design. Reviews. Case reports.	
Publication language	English language.	
Participants	Adults (19 years and above). Any gender.	Children and adolescents.
Disorder	Any type of AUD. AUD comorbid with physical disorder.	AUD comorbid with any other substance use disorder or mental disorder.

4.2.3 Data screening

The titles of the papers identified through the electronic database search were screened and the abstracts of relevant papers were retrieved. These abstracts were examined for possible inclusion and full texts of selected papers were then retrieved. These full texts were then examined to determine their eligibility for inclusion in the review. Full texts of papers identified in the libraries and recommended by key informants were examined for eligibility.

4.2.4 Data extraction and analysis

Selection of papers, and data extraction were conducted by one reviewer and consultation sought when necessary with another reviewer who was blind to the opinion of the first reviewer. Data were extracted into an a priori designed data extraction table made using Microsoft Excel.

The data were analysed qualitatively using thematic analysis, a method for identifying, analysing, and reporting patterns (themes) within data (Boyatzis, 1998). Data analysis progressed from applying a set of predetermined categories to data (deductive analysis) to the process of generation of codes from raw data (inductive analysis) (Fereday et al., 2006). Two predetermined categories were used for analyses, adapted from Kleinman's schema (Kleinman et al., 1978) namely illness mechanism and cause, and help seeking behaviours.

4.3 Results

1506 records were identified through the search of electronic databases. Through a process of stepwise screening ten articles were selected for this review. To this number, one article each from the parallel search for psychosocial interventions of AUD in India (Ghulam et al., 1996) (Chapter 3) and the grey literature search (Anitha, 1999) were added. Thus, a total of 12 articles have been included in this review (See Figure 4.2 for details).

Table 4.2 presents details of studies included in this review. These included four qualitative studies (Chowdhury et al., 2006; Gururaj, 2006; Jayaram et al., 2003; Nimmagadda, 1999) and observational quantitative studies viz seven cross sectional surveys (Anitha, 1999; Ghulam et al., 1996; Girish et al., 2010; Malhotra et al., 1999; Meena et al., 2002; Perera and Torabi, 2009; Yousafzai et al., 2009) and one case control study (Gaunekar et al., 2005). One study each was conducted in Pakistan (Yousafzai et al., 2009) and Sri Lanka (Perera and Torabi, 2009); the rest were all conducted in India. The studies were conducted in community settings (urban, rural, slum) (Ghulam et al., 1996; Girish et al., 2010; Gururaj, 2006; Jayaram et al., 2003; Meena et al., 2002; Perera and Torabi, 2009; Yousafzai et al., 2009), an underserved and backward delta region (Sunderban) in West Bengal, India (Chowdhury et al., 2006), industrial units (Gaunekar et al., 2005), and addiction treatment centres (Anitha, 1999; Malhotra et al., 1999; Nimmagadda, 1999). The sample size ranged from 8 to 5236 and the participants included community dwelling male and female drinkers/non-drinkers, medical students, other students, unskilled workers, skilled workers, professionals and alcohol dependent patients.

Figure 4.2: Flow diagram of studies included in the systematic review of explanatory models

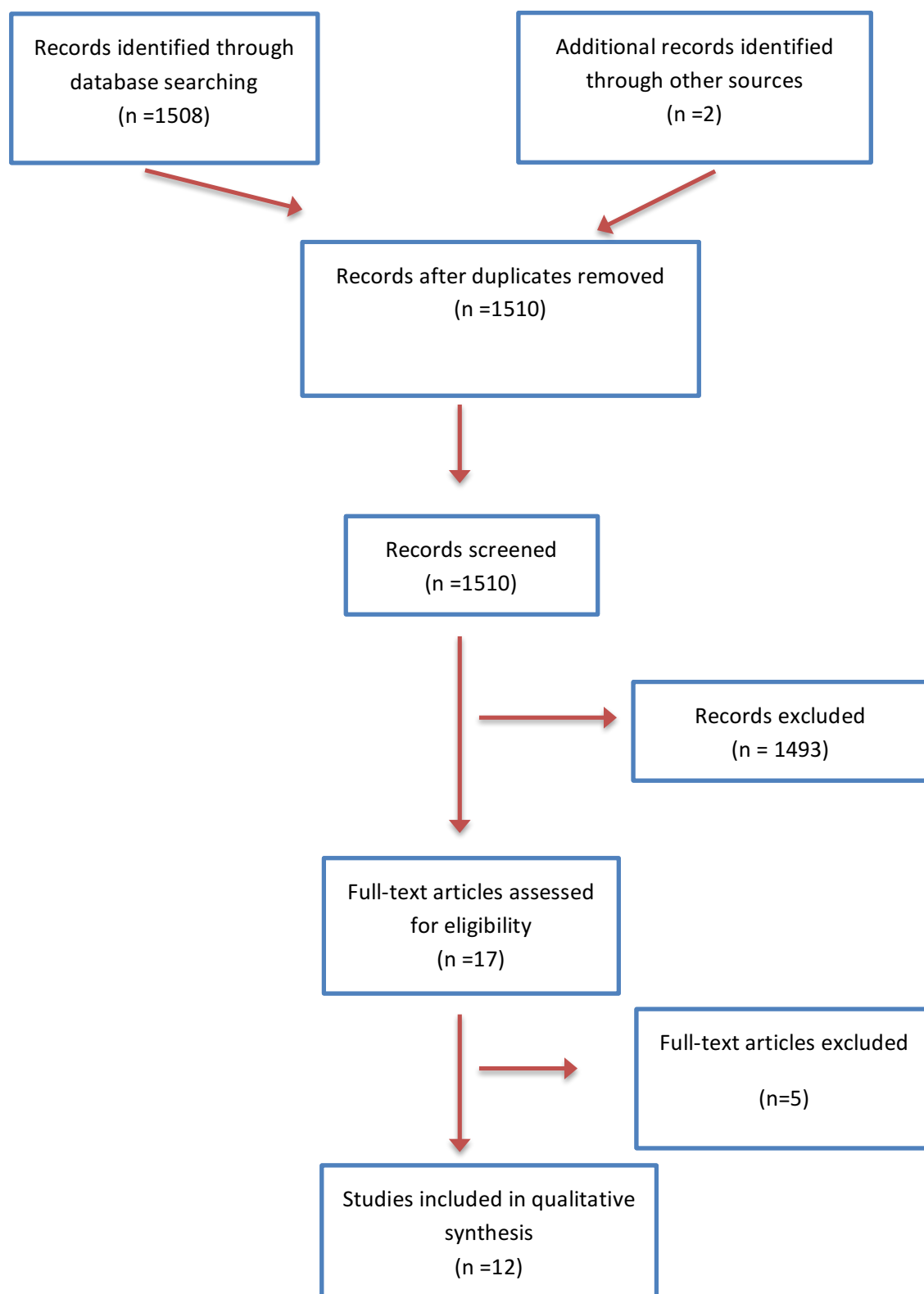


Table 4.2: Details of studies included in the review

Author, Year	Study design	Setting	Sample
Girish, 2010	Cross sectional survey	Urban, rural, slum, town settings in Bangalore district, India	Male, female. N=28507 of which 2350 were drinkers.
Perera, 2009	Cross sectional survey	Community, Sri Lanka	Male drinkers. 16-30 years. N=412
Yousfazai, 2009	Cross sectional survey	Community, Pakistan	Male and female medical students. N=342
Gururaj, 2006	Focus Group Discussions (FGD) nested in a cross sectional survey	Urban, rural, slum, town settings in Bangalore district, India	One FGD (n=16-25) each in town, rural and slum areas. The slum group consisted exclusively of women, while the others were mixed groups.
Chowdhury, 2006	In-depth Interviews (IDI), FGD	Sunderban, an underserved and backward delta region in West Bengal, India	Group interviews were conducted in single sex and mixed groups; with groups organised according to age, occupation, religion, and marital status. An average of 9–10 group interviews per village and a total of 88 in-depth

Author, Year	Study design	Setting	Sample
			interviews were conducted.
Gaunekar, 2005	Case control study	Industrial units, Goa, India	Males N=984
Jayaram, 2003	Qualitative study with semi structured interviews	Community, India	Male and female students, unskilled workers, skilled workers and professionals. N=120
Meena, 2002	Cross sectional survey	Community, Rohtak, India	Males. 14 years and above. N=4691 (928 alcohol users)
Anita, 1999	Cross sectional survey	Addiction centre, India	Male and female inpatients and outpatients. N=100
Malhotra, 1999	Cross sectional survey	Addiction centre, India	Alcohol dependent men. N=30

Author, Year	Study design	Setting	Sample
Nimmagadda, 1999	IDI, FGD	Addiction centre, India	Alcohol dependent men. N=8
Ghulam, 1996	Cross sectional survey	Community, Madhya Pradesh, India	Male and female. N=5236

4.3.1 Causal beliefs and illness mechanism

Four broad themes emerged as causal attributions for alcohol use: psychological causes, socio-cultural causes, functional use and drinking for pleasure.

i) Psychological causes

Alcohol as a means of reducing stress emerged as an important cause for drinking. In a sample of young male drinkers, reduction of 'tension' (stress) was a stronger motive for alcohol consumption than peer pressure and social enjoyment (Perera and Torabi, 2009). In another sample of similarly young, medical students, alcohol was seen as an effective strategy to reduce stress (Yousafzai et al., 2009).

The perceived stress leading to drinking was reported to be due to a host of reasons. A group of young men observed that the poor economy, lack of job opportunities, and family disputes frustrate youngsters, and they cope by drinking to forget such problems (Chowdhury et al., 2006). In a household survey, a fifth of the drinkers reported financial and family problems as the reason for drinking (Girish et al., 2010). In another sample of drinkers, drinking was seen as a way to 'overlook worries and frustrations' (Meena et al., 2002).

Malhotra et al (1999) examined the reasons for relapse and reported that the most common precipitants attributed by patients and relatives were reduced cognitive vigilance ('when already taken some drink'; 'thinking that not really hooked on alcohol'; and 'thinking that just one drink won't harm'), and euphoric as well as unpleasant mood states (Malhotra et al., 1999).

ii) Socio-cultural causes

Peer pressure was seen as an important factor leading to drinking and the subsequent development of AUD. Peer pressure was reported as a key reason for starting drinking, promotion and sustaining of drinking and development of dependence (Chowdhury et al., 2006; Girish et al., 2010).

Alcohol use was associated with both increasing and decreasing income and socioeconomic status. Among workers from the lower socioeconomic strata,

drinking was seen to result from increasing wages and disposable income. *'Labourers may now earn as much as Rs. 60 per day, enabling them to easily spend Rs. 20 on alcohol. Tiger prawn seedling collection produced unprecedented income for teenagers, and they routinely spend a portion of that on drinking'* (Chowdhury et al., 2006). Besides increasing wages contributing to drinking, alcohol itself was observed to be a currency in social rituals and for financial transactions in this socio-economic stratum. *'Chullu (locally brewed alcohol) serves as currency in social rituals and as payment in financial transactions. For example, a foreman who prepares the soil bed and plants betel leaf vines may receive two to three bottles of chullu as part of his remuneration'* (Chowdhury et al., 2006).

On the other hand, among the higher socio-economic strata the use of alcohol was seen as a symbol of higher economic status as seen in the following vignette: *'I grew up in a home without any alcohol. My father was a clerk in the state government office and my mother was a housewife. We did not see much money. Brought up in a home without much luxury makes me react to money differently. Serving alcohol at home, storing alcohol at home, and drinking alcohol is a way I show off. I want to let the world know that I have made it'* (Nimmagadda, 1999). In the higher income groups, drinking alcohol was seen as a way of life and was described as a *'social ritual'* which on further exploration was elaborated as follows: *'Oh! You know, coming in the evening, sit around and have a peg'* (Nimmagadda, 1999). Furthermore, drinking in higher socio-economic groups was viewed to be less socially disruptive as people from these groups were thought to be more sensitive to the loss of social prestige and it was believed that this discouraged public drunkenness in these groups (Chowdhury et al., 2006).

AUD were also perceived as one's fate or 'karma'. The law of 'karma' that has considerable influence on the lives of Hindus, states that the fortunes and misfortunes of one's current life result from the good or evil deeds in a previous life. AUD is seen as a punishment for past misdeeds as elaborated in the following vignette *'Alcoholism to me means something that I deserved. I am getting what I have to; almost like getting my fair share in life. I must have done something wrong in my past to get addicted to alcohol'* (Nimmagadda, 1999).

iii) Drinking for pleasure

Drinking alcohol as an activity for pleasure and socialising was rarely reported. Although some drinkers saw it as a way to be sociable or to enjoy (Ghulam et al., 1996), the number of people reporting this was very small with only 10% consuming alcohol as a pleasurable activity (Girish et al., 2010), to be sociable (26%), to relax (7%), and to cheer up (14%) (Meena et al., 2002).

iv) Functional use of alcohol

Alcohol was commonly used as self-medication to alleviate pain, reduce tiredness and induce sleep especially amongst manual labourers (Ghulam et al., 1996). Men whose livelihood required heavy labour (such as pond diggers, van pullers, and tiger prawn seedling collectors) found drinking chullu (locally brewed alcohol) especially appealing and explained that drinking chullu at the end of the day brought relief from body aches and pain (Chowdhury et al., 2006). A manual labourer described the pain relieving or 'numbing' effect of alcohol thus: *'I am on my feet all day. Carry heavy loads and work in the hot sun. My body aches by evening. My legs are tired. Alcohol to me means numbing that pain'* (Nimmagadda, 1999).

A summary of findings from the studies included in this review is presented in Table 4.3.

Table 4.3: Summary of causal beliefs and illness mechanisms

Themes	Sub themes	Author, Year
Psychological causes	<ul style="list-style-type: none"> • Reduction of stress due to financial reasons, lack of job opportunities, and family problems. • Relapses attributed to reduced cognitive vigilance and mood states. 	Girish, 2010; Perera, 2009; Yousafzai, 2009; Chowdhury, 2006; Meena, 2002; Malhotra, 1999
Socio-cultural causes	<ul style="list-style-type: none"> • Peer pressure • Increasing and decreasing socioeconomic status. • Currency in social rituals and for financial transactions in lower socioeconomic strata. • 'Social ritual' in higher socioeconomic strata. • Drinking perceived as less socially disruptive in higher socio-economic groups. • Perceived as one's fate or 'karma'. 	Girish, 2010; Chowdhury, 2006; Nimmagadda, 1999
Drinking for pleasure	<ul style="list-style-type: none"> • Means to be sociable or to enjoy. 	Girish, 2010; Meena, 2002; Ghulam, 1996
Functional use	<ul style="list-style-type: none"> • Self-medication by manual labourers to alleviate pain, reduce tiredness and induce sleep. 	Chowdhury, 2006; Nimmagadda, 1999; Ghulam, 1996

4.3.2 Help seeking

The included studies described the help-seeking patterns of people with varying severity of drinking problems. Among community dwelling drinkers, 53.3% did not feel the need to reduce drinking, 13.2% thought about getting help regarding drinking and only 5.1% actually approached the doctor (Gururaj, 2006). Of this small proportion, the doctor advised 52.9% to cut down on drinking. Among hazardous drinking workers in industrial units 6% had sought help for their drinking at some point of time; and most often this was from friends/family or the company doctor (Gaunekar et al., 2005). The common settings where patients initially sought help included general practitioners (57%), general hospital doctors (45%), private psychiatrists (11%) and native healers (17%) (Anitha, 1999). Half the patients did not know that alcoholism was a bio-psycho-social problem for which specialized intervention was available (Anitha, 1999). Participants reported that doctors generally say 'do not drink', but the former reported needing more help than that to quit the habit (Gururaj, 2006). In a study of 100 consecutive inpatients and outpatients seeking help for alcohol dependence at a specialist addictions treatment centre 15% of patients had directly accessed the specialist centre; the rest had been referred by a general practitioner or hospital doctor (Anitha, 1999).

4.4 Output

Psychological causes, socio-cultural causes, and functional use of alcohol were primarily perceived to be the causes of drinking and drinking problems. Furthermore, there was a general lack of understanding about the biomedical perspectives of AUD and the help available; and poor access to care for the small numbers that wanted to help.

Similar explanations for drinking and related problems have been reported in studies from other countries. Peer influences (Kuntsche et al., 2005; Yan et al., 2008), psychological stress due to a host of reasons (Brady and Sonne, 1999) and subjective pain relief (Brennan et al., 2005; Cutter et al., 1976) have all been shown to be associated with the onset of AUDs in populations in western countries. One of the interesting findings is the simultaneous causal attribution of both prosperity and financial stress with AUD. The understanding of such an apparent contradiction is perhaps particularly important in LMIC where poverty

and prosperity exist in close proximity. This association of AUDs with both prosperity and deprivation reflect an interesting finding that while wine and beer consumption, in general, reflect prosperous and stable periods, that of distilled spirits reflects long term prosperity as well as short term economic stress (Brenner, 1975).

It is important to note that all steps of the treatment development process do not necessarily contribute potential components to the developing treatment. Some steps contribute the content (e.g. the systematic reviews described in Chapters 2 and 3), some enhance the confidence in the potential acceptability and feasibility of the identified evidence based components (e.g. the systematic review described in this chapter), some do both of the above (e.g. the qualitative study described in Chapter 5), and some test the assumptions made from the previous steps (e.g. the case series and pilot RCT described in Chapters 8 to 10). Thus the treatment development process is not built on independent steps but involves triangulation of data from the various steps. An example of that is the observation that some of the findings of this review lend themselves to being managed using a range of psychosocial strategies identified in the reviews described in Chapters 2 and 3. For example, as 'lack of awareness about alcohol problems and availability of treatments' was one of the findings and the 'psycho-education' strategy identified in the regional literature review could be one of the important components of the intervention being developed. Table 4.4 highlights how the findings of this review support the use of some of the strategies identified in the international and local reviews of literature.

These findings along with those from the previous steps and the subsequent step (described in Chapter 5) would then be taken forward to the step described in Chapter 6 to select the psychosocial strategies that are effective, acceptable and safe to be delivered by NSHWs.

Table 4.4: Findings from the explanatory models review that support the use of strategies identified in the reviews of international and local evidence for psychosocial interventions for AUD

INTERVENTION STRATEGY	SOURCE			
	mhGAP	LITERATURE REVIEW		
		International	Local	Findings from the Explanatory Models review which could respond to strategies identified in the previous steps
Personalised feedback		✓	✓	
Motivational Interviewing	✓	✓	✓	
Cognitive restructuring	✓	✓		
Psycho-education			✓	Lack of awareness about alcohol problems and availability of treatments.
Support groups			✓	
Relapse prevention			✓	'External situations, euphoric states and unpleasant mood states which were seen as triggers for relapse'
Social skills training			✓	Peer pressure was seen as an important reason for starting and maintaining drinking behaviours.
Family psycho-education			✓	Lack of awareness about alcohol problems and availability of treatments.
Family counselling			✓	Family problems seen as one reason for drinking alcohol.
Religious and spiritual practises			✓	For stress management.

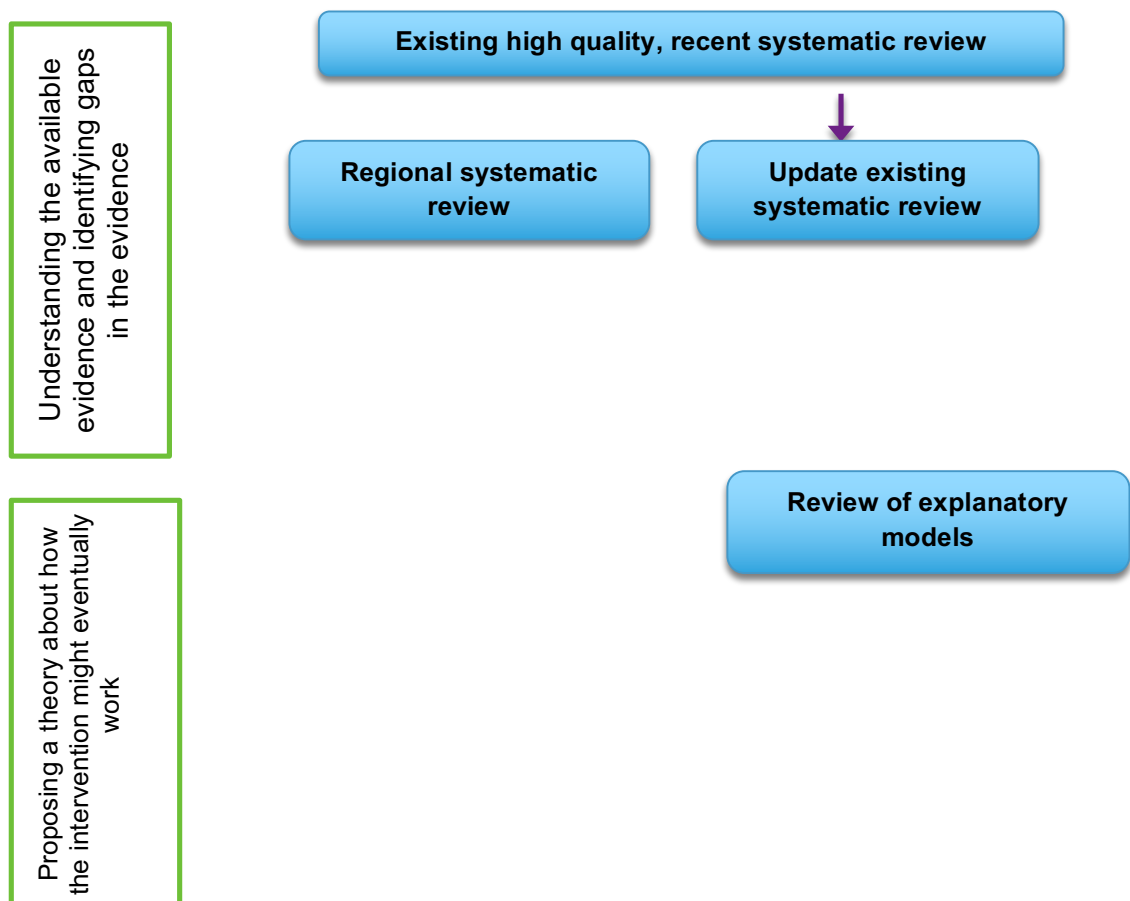
INTERVENTION STRATEGY	SOURCE			
	mhGAP	LITERATURE REVIEW		
		International	Local	Findings from the Explanatory Models review which could respond to strategies identified in the previous steps
Kundalini Yoga			✓	For stress management.
Addressing interpersonal issues with one's partner			✓	Family problems seen as one reason for drinking alcohol.
Befriending			✓	

Chapter 5 Explanatory models of AUD: Qualitative study^{**}

5.1 Background

In the previous chapter I described the explanatory models for Alcohol Use Disorders (AUD) in South Asia through a review of literature and examined how they could be used to support the development of a contextualised psychosocial intervention for AUD (Figure 5.1). As explanatory models are not immutable it is possible that the explanatory models for AUD in the study region (Goa and Satara) could be partly or fully different from those in the wider region (South Asia). Hence, to examine local explanatory models, a qualitative study was conducted and is described in this chapter.

Figure 5.1: Progress of the intervention development process



^{**} Author contribution to the methods: I analysed the data, synthesised the results, and interpreted the findings. Some of the content of this chapter has been directly extracted from my published paper Nadkarni A, Dabholkar H, McCambridge J, Bhat B, Kumar S, Mohanraj R, et al. The explanatory models and coping strategies for alcohol use disorders: An exploratory qualitative study from India. Asian Journal of Psychiatry. 2013;6(6):521-7.

Besides understanding the explanatory models of AUD, the qualitative study had other objectives like understanding coping strategies employed by men with AUD and their family members, examining various psychosocial strategies delivered by health professionals, and treatment outcomes desired by men with AUD and their family members. A better understanding of these would inform the goals of the developing psychosocial intervention and selection of contextualised psychosocial strategies from the previous steps. The objectives of this study and the rationale of the objectives of this step of the intervention development process are as described in Table 5.1 below.

Table 5.1: Objectives and rationale of the qualitative study

Objective	Rationale
To explore the explanatory models of patients with AUD and their family caregivers.	To inform the developing psychosocial intervention in terms of providing appropriate avenues for treatment negotiation.
To explore and define self-help and coping strategies used by patients with AUD and their family caregivers.	To incorporate perceived beneficial strategies into the developing psychosocial intervention.
To define and describe forms of psychological and other help sought by patients with AUD.	To use this information to form the basis for choosing strategies on which the developing psychosocial intervention would be modelled.
To explore and define treatment expectations and desired outcomes of the patients with AUD and their caregivers.	To inform the goals of the developing psychosocial intervention.

5.2 Methods

5.2.1 Study sites

The two sites for data collection were Goa and Satara in India. Details about these two sites are provided in Chapter 1.

5.2.2 Sample

Interviews with patients with AUD, their family members and health care providers were carried out in Goa and Satara. In addition, interviews with healthcare providers from other parts of the country were also conducted.

There were three groups of participants:

- a) Patients with AUD: Adult (above the age of 18 years) males who were diagnosed to have AUD by a trained healthcare provider, viz. psychiatrists or de-addiction centre counsellors;
- b) Significant others (SO): Persons living with patients with AUD, and who were judged by them or their health care provider to play an active role in caring for the patient. These could or not be relatives of the AUD participants; and
- c) Health Care providers (HCP): Any person who was engaged in treating patients with AUD. They were further categorised into:
 - i) Mental health specialists: These were professionals who were qualified in the field of mental health care and were specialists in the delivery of mental health interventions e.g. psychiatrists, clinical psychologists and psychiatric social workers.
 - ii) Formal non-specialist care providers: These were professionals who were not qualified mental health specialists but provided care within the formal healthcare system e.g. general physicians, nurses, Ayurveda (traditional Indian medicine) or Homeopathy practitioners.
 - iii) Non-formal care providers: Such providers worked outside the formal healthcare system and included people like religious healers, meditation trainers and Yoga therapists. As a large proportion of people with AUD do not access formal healthcare services for their alcohol problems, we believed that this group would also help us with identifying locally available and culturally appropriate intervention strategies on which there was limited or no information in published literature.

5.2.3 Sampling strategy

Purposive sampling, also known as judgment sampling, refers to a sampling strategy in which the researcher actively selects the most productive sample to answer the research question (Marshall, 1996). This sampling strategy was used to recruit participants for the study to ensure that data were obtained from participants who possessed the characteristics that were most relevant to achieving the research objectives.

Furthermore snowball sampling (participants are asked to recommend more people who might be useful potential participants for the study) (Marshall, 1996) was also used to identify more HCPs. HCPs who could potentially provide rich information were selected by inviting eminent and well known experts in the field of addictions and psychiatry based on the suggestions of the research team. These HCPs were then asked to recommend and refer other HCPs to be contacted for participation.

5.2.4 Sample size

The aim was to select 20-30 each of patients with AUD, SOs and HCPs. As this was a qualitative study these numbers were not derived from sample size calculations and the plan was to stop data collection once data saturation was reached i.e. no new data emerged.

5.2.5 Data collection

Data were collected through in-depth interviews (IDIs), a technique that allows for detailed in-depth probing of subject matter and provides information on context (how experiences are linked to each other) (Legard et al., 2003). Individual interviews were conducted instead of focus group discussions as they allow participants more freedom to express their thoughts, especially regarding sensitive issues related to drinking problems as well as about limitations of interventions received.

5.2.6 Interview guide

The interview questions were guided by the research objectives and for each research objective there was a set of questions designed to explore that objective. Consistent with the nature of qualitative research these questions were open-ended and flexible, with the flow of the interview within each topic

being determined by information provided by the participants. However, the interviewer retained overall control of the interview to ensure that the information being provided by the participant was consistent with achieving the research objectives but at the same time permitted further probing of unexpected findings.

Based on the research objectives, an interview framework (a table of broad interview topics and questions to address these) was developed. This framework served as a template for developing open-ended questions and probes for the interview guides.

The list of topics for interviews with patients with AUD and SOs were as follows:

- a. Perceptions of the illness (of the problem, causes, and risk factors);
- b. Self-help and coping strategies;
- c. Help seeking behaviours with family, formal HCPs and non formal HCPs; and
- d. Specific psychosocial strategies, and perceived benefits and acceptability of these.

It was important to explore the explanatory models rather than focusing on the more simpler 'what was helpful?' question. As the access to services for AUD in India is limited both in terms of coverage (i.e. primarily concentrated in tertiary care in urban areas) and content (i.e. primarily biomedical treatments) any responses to 'what was helpful?' would be limited to what we already knew. On the other hand, focusing on the broader topics outlined above would allow us to explore what is available, what appears to work, what are the felt needs, and what existing self help strategies could be formalised into an intervention to make it more acceptable and effective.

The topics for HCP interviews were:

- a. Experiences in the management of AUD;
- b. Specific psychosocial strategies and techniques delivered and their perceived impact;

- c. Health seeking behaviours of persons with AUD in general; and
- d. Views on acceptable modes of delivery, especially delivery by NSHW.

This framework was then used to develop three IDI guides, one for each set of participants. This was done by adding various open-ended questions and probes to the initial framework and structuring the interview in a manner that enabled a smooth flow between questions and topics. Appendix 3 describes the final interview guides for patients with AUD, SOs and HCPs. The interview guides were developed in English and then translated into the two local languages i.e. Konkani for Goa and Marathi for Satara.

Besides administering the interview guides the following data were also collected:

- a. Participant's socio-demographic details;
- b. Notes made during the interview regarding
 - i. Content of the interview e.g. statements made by the participants which could be used as potential probes in future interviews; and
 - ii. Non-verbal behaviour e.g. eye contact, posture, and facial expressions.
- c. Summary of the main findings of the interview from the interviewer's perspectives as well as information about the field visit (e.g. setting, privacy and space available, participant's attitude towards the interview); and
- d. Impressions about the interview guides.

These data were used to contextualise the information from the IDIs and to add to its richness, as well as to iteratively refine the interview guides.

5.2.7 Data collection

Fourteen research workers conducted the IDIs across the two sites. All research workers were graduates; nine were mental health specialists or were experienced in the field of mental health and the rest were graduates in other professions. Two research workers had prior training in qualitative research;

and the rest underwent a three-day training workshop in qualitative data collection organized by two qualitative research experts. During the workshop, the team became familiar with the research objectives and acquired the necessary skills for conducting IDIs under supervision. A series of role-plays of IDIs supervised by experienced members of the team were held before data collection. Subsequently, two-day refresher training workshops with the research workers were held on two separate occasions while the study was underway, in which interviewing techniques were critiqued using tapes of interviews that were already conducted, role-plays were conducted, and recommendations made for future interviews.

Participants were either contacted directly by the research workers or through their HCPs. All patients with AUD and SOs were interviewed face to face either at their homes or at the HCP's premises. HCPs were interviewed face to face or over the telephone. Written informed consent was taken individually from all participants. Permission to record the interview sessions on the digital audio recorder was sought from each participant prior to the interview.

5.2.8 Supervision and quality control

The quality of data was monitored on an on-going basis through the following mechanisms:

- a) For the first 10 interviews the research coordinator examined in detail each individual transcript of the interview and checked it for richness and quality of data and interviewing style. Written feedback was then provided to the relevant research worker with suggestions for improvement and questions to be emphasised in subsequent interviews. The research coordinator also assessed each researcher independently for his/her strengths and weaknesses in interviewing style and provided recommendations for improvement.
- b) Three randomly selected transcripts of interviews were sent to the two qualitative research experts in the team for their comments and suggestions on both the interview quality as well as feedback given by the research coordinator.

- c) The research coordinator had weekly or fortnightly meetings with the research teams at each site to discuss and resolve issues regarding their interviewing skills, use of interview guides, and other field issues.

5.2.9 Data management

All audio-recorded interviews were first transcribed verbatim and then translated into English by a bilingual data entry operator (fluent in both English and the local language). The transcriptions were checked by the interviewer for grammatical and other errors and edited further taking care to retain the local flavour (e.g. idiosyncratic terms explained in brackets).

Only research team members had access to the data. Hard copies of data were stored in a locked cabinet. The transcribed and translated electronic versions of the participant interviews were saved as password protected files in computers. Each participant was given a unique ID and all identifying information was removed from the electronic transcript. Identifying documents were kept separately in locked cabinets. Data was regularly backed up on a centralized server, and was password protected with access only to the research team.

5.2.10 Data analysis

Data was analysed using thematic analysis, which is a method for identifying, analysing, and reporting patterns (themes) within data (Braun and Clarke, 2006). In this method, data analysis progresses from applying a set of pre-determined codes to data (deductive analysis) to the process of generation of codes from raw data (inductive analysis) (Fereday and Muir-Cochrane, 2008).

The analysis was a combination of deductive and subsequently inductive (through thematic analyses) strategies. Initially, a set of pre-determined codes, namely perceptions of the illness; self help strategies used to cope with the illness; help seeking behaviours; and psychosocial interventions sought/provided and interventions provided in the local context were developed based on some of Kleinman's Eight Questions, a well established theory of explanatory models (Kleinman et al., 1978), and were deductively applied to the data. Subsequent analysis involved inductive generation of new codes from raw data. These codes were used to generate a new coding template, which was then applied to the remaining interviews. Codes were then compared with each

other for similarity in meaning. Similar codes were collapsed into inclusive categories and clusters of related codes were organised under other codes, forming hierarchies. Themes are “general propositions that emerge from diverse and detail-rich experiences of participants and provide recurrent and unifying ideas regarding the subject of inquiry” (Bradley et al., 2007). Themes were derived by retrieving pieces of data pertaining to codes and by examining their meaning in relation to the research questions. Patterns were derived by eliciting similarities and differences between themes generated from interviews of men with AUD and SOs to get a better understanding of where they converged or diverged. Each theme was assigned a name and a descriptive phrase that best explained their meaning and united its individual codes on consistency (for example, the label “cognitive restructuring” was given to all interventions that aimed to change patterns of thinking). Similarly, for psychosocial strategies described by HCPs, appropriate ‘biomedical’ labels were applied based on the description of the strategy provided by the particular HCP e.g. a strategy which was delivered by a HCP using techniques like open ended questioning, reflection, and affirmation was labelled as Motivational Interviewing (MI). This was done to map the strategies used locally to the international biomedical literature. The themes were supported by excerpts from transcripts to demonstrate that themes were as close to the data as possible and reflected the words used by the participants themselves. Finally, a list of themes was made and organised according to the research question they answered.

5.3 Results

IDIs were conducted with 72 participants. Of these, 29 were men with AUD, 10 were SOs and 33 were HCPs (Table 5.2). The men with AUD were middle aged and the majority had completed high school, were married and employed. The SOs predominantly were female, middle aged and a large proportion had completed high school and were employed. All, but one (parent), SOs were wives of men with AUD. The HCPs were middle aged and predominantly were male. Of the HCPs, 24.2% were mental health specialists, 42.4% were formal non-specialist HCPs, and 33.3% were non-formal care providers.

Table 5.2: Socio-demographic details of participants

Variable	Patients with AUD (n=29) n (%)	Significant Others (n=10) n (%)	Healthcare providers (n=33) n (%)
Mean age	42.1	38.8	49.3
Gender			
Male	29 (100)	1 (10)	23 (69.6)
Marital status			
Never married/Post marital	2 (6.8)	1 (10)	9 (28.1)
Married	27 (93.1)	9 (90)	23 (71.9) mv=1
Education (number of years)			
Illiterate	0 (0)	1 (10)	
Less than 10 years	7 (25.9)	4 (40)	
More than 10 years	20 (74.1) mv=2	5 (50)	
Employment status			
Employed	24 (82.7)	7 (70)	
Unemployed	5 (17.2)	3 (30)	
Relation with patient			
Spouse		9 (90)	
Parent		1 (10)	

Variable	Patients with AUD (n=29) n (%)	Significant Others (n=10) n (%)	Healthcare providers (n=33) n (%)
Profession			
Mental health specialist			8 (24.2)
Non-specialist formal			14 (42.4)
Non-formal			11 (33.3)

mv=Missing values

The sub themes from the interviews are described below under the following themes:

- Explanatory models or perceptions about the disorder;
- Self help coping strategies;
- HCPs and intervention settings;
- Non pharmacological intervention strategies and techniques;
- Outcomes desired from treatment; and
- Desired treatments.

5.3.1 Explanatory models

a) Progression of AUD

The journey from being an occasional or casual drinker to developing AUD was a slow and insidious one with patients often describing tolerance and a gradual progression from drinking low alcohol content drinks to spirits and eventually country liquor. One participant eloquently described the progression to AUD as follows: *“For seven years I drank alcohol in a controlled manner, from the age of 19 to 26 years.....till 26 years I drank in a controlled manner. This is a progressive disease that goes on worsening one beer became two beers. Later, as beer*

was expensive, I resorted to having hard drinks (spirits). Since these too were expensive, I started taking desi (country liquor). I used to drink till I got a kick (high) and then I would feel better. I continued drinking like this for many years. I started beating my wife and children, I would fight with my neighbours, would fall on the road, and sometimes injure my head.....I became an alcoholic” (Male, 35 years)

b) Symptoms of AUD

Patients clearly described the symptoms of alcohol withdrawals and compulsion to drink. As one participant said, *“If I did not drink I would shake (tremors), my heart would beat faster, I would get acidity, and I could not function. Then I would have that drink.....now I am explaining to you the compulsive alcohol behaviour....then I would start craving. I wanted a little more, I wanted a little more, I wanted a little more” (Male, 42 years).*

Feelings of guilt, of despair and a desire to give up alcohol were expressed but these were usually short lived and the men with AUD felt that they could not stop even if they wanted to. One participant said, *“I used to feel like stopping my drinking. I wanted to leave alcohol but there was no way out, I didn’t know what to do. I used to regret what I did the previous night (after drinking)..... I had beaten my wife, now what should I do? I used to feel ashamed of what I did in the night. I would then tell myself that I would drink only today and give up drinking from tomorrow. I never decided I would give up from today. It was always tomorrow” (Male 42 years).*

Another participant described how his drinking had taken such a hold over his life to the exclusion of everything else including his family. He said *“They (family members) used to keep me away from them. I would not go to them either.... I wanted only alcohol..... I was in my own world. I would not bother about others and they would not bother about me. When I met them on the street they would not greet me and I would not greet them either. I had my own group of drinking companions with whom I could sit and talk and do whatever I wanted. I was not interested*

in what was happening around me” (Male, 30 years).

c) Perceived impact of drinking

The participants described how their drinking affected various domains of their lives. The impact was primarily seen to be on social life, family life, health, and family finances.

- i. Social life: Alcohol was seen both by the men with AUD and SOs as leading to the breakdown of social networks. A man with AUD reported the following; *“I may have broken off with a few people! After drinking alcohol I must have said something to them and they may have become upset”* (Male, 37 years). The husband’s drinking problems also adversely impacted the wife’s social life. One wife said, *“It has become difficult for me to call my friends home. They call me a lot to their houses but if I go to their house then I will also have to invite them to our house. If they come home and he (husband) is drunk...it is not something that I would want them to see”* (Female, 43 years, Spouse).
- ii. Family life: Some men with AUD expressed a deep sense of sorrow and regret when they described the effect their drinking had on their family. One man said, *“for some reason or the other I would argue with her (mother). I would beat her and sometimes abuse her. That was the main tragedy; that I did that (argue and beat) even to my mother”* (Male, 48 years). Similarly the disruptive effect of drinking on marital life was described thus, *“My wife used to get angry when I would come home drunk and then we would argue. Everyone started drifting away from me. My wife left me and has gone to stay with her parents”* (Male, 42 years). One SO said, *“If his (husband) friends came home, it used to become very difficult for me. I would be tensed thinking that he would insult me in a drunken state. When one is drunk, one treats others as inferior. Many times he (husband) has insulted me in front of outsiders in a drunken state”*, (Female, 41 years, Spouse).

The SOs were equally worried of the impact their husband’s

behaviour had on their children. The children felt ashamed of their father and feared calling their friends home, described thus by the wife of a man with AUD, *"I told him (son) that if you go and study with your friends you would study well. But he said that if he went to his friends' homes he would have to invite them to our home. He was worried that if his friends saw his father like this (drunk) then everyone in his class will come to know"* (Female, 28 years, Spouse). Some men were aware of the impact their drinking had on their children. One man with AUD said *"I used to drink in the evenings; they (family) would express their discontent about it. I could not become an ideal father; I could not give good values to my children"* (Male, 65 years).

- iii. Health impact: Expectedly most of the men with AUD and SOs reported a negative effect of drinking on either mental or physical health. One man reported *"A couple of days after drinking I suffer from heavy headache and I need to see a doctor. Also I have become slightly obese. I used to be fit before but due to alcohol my fitness has reduced. Due to this addiction I also experience a few stomach problems"* (Male, 37 years). Alcohol was also reported to have an adverse impact on the mental health as reported by this participant: *"My head used to get....like mental and I would find it difficult to recognize people. I used to feel irritated and angry with everybody. I used to get unwanted thoughts..... she's (wife) not at home today, maybe she has left me and gone"*, (Male, 45 years).
- iv. Financial impact: Most SOs and also men with AUD reported at least some impact on their finances because of diversion of essential household funds to drinking. One man said, *"Yes, there is financial impact.....because we spend some amount of whatever we earn on drinks. Sometimes, instead of money, people offer us drinks for the work we do for them"* (Male, 37 years). Another man reported that alcohol affected only his finances and no other domain of his life. He said, *"Only my expenditure has increased (due to alcohol). . . there are no other problems due to drinking. . .I have only experienced some effect on the family expenditure"* (Male, 52 years).

d) Causal attribution

Men with AUD and SO broadly attributed their alcohol use to psychosocial causes, peer influences, availability of disposable income and drinking for pleasure.

- i. Psychosocial stresses: Psychosocial stressors, attributed primarily to financial problems and family disturbances, were perceived to lead to AUD. One man with AUD described the impact of financial loss in a business venture on his drinking thus: *“I incurred a major loss of about eight lakh rupees (approximately 8000£) and I had to wind up that business. Subsequently, out of frustration I took to drink. All of a sudden, from earning 70 to 80 thousand rupees (approximately 700-800£) in a month, I did not have even hundred rupees (approximately 1£) in my pocket... (It was) quiet frustrating”* (Male, 36 years). Problems in the family environment were also commonly recognised as a major factor leading to drinking problems. One participant attributed his drinking problems to the stress caused by his wife’s extramarital affair. He said *“I came to know (about wife’s extra marital affair). From that time my mind was upset and I did not know that alcohol is a disease.....it is like a sickness. I thought you just drink it and then forget about it. But it gives only temporary relief”* (Male, 45 years).
- ii. Peer influences: Peer pressure was reported as one of the key reasons for starting drinking, sustained alcohol use or for developing alcohol dependence. Many participants described their drinking starting in social settings and in such settings peer influences played a significant role on initiation of drinking as well as the evolution of drinking problems. A farmer describing his after work routine said the following, *“After farming work is over, things like alcohol and meat (consumption) begin. In this activity, even if we are not willing, we have to participate on the insistence of others”* (Male, 40 years). SOs also acknowledged the role of peer influences in the development of AUD. A wife describing her husband’s drinking said, *“Yes, I asked him (husband). . .Why do you drink? Is there any tension related to*

wife or children? Why? And he told me, 'No I drink with my friend circle' (Female, 30 years, Spouse).

- iii. Availability of disposable income: Alcohol consumption was often seen as a status symbol and representative of economic status. The availability of disposable income was perceived as leading to drinking and development of AUD by some men with AUD. SOs agreed that easy availability of money to spend was responsible for their husbands' drinking problems. *"If a person gets more money than necessary in his hands, then the person starts getting inclined in such direction.....using money this way (to buy alcohol). He then falls prey to addiction"* (Female, 43 years, Spouse). Describing a similar situation, another SO added that, *"There can be a lot of different reasons (for drinking alcohol). When someone has a lot of money, he doesn't understand when and how to spend it?"* (Female, 28 years, Spouse).
- iv. Drinking for pleasure: Drinking for personal enjoyment was not a commonly reported motive for drinking. A man with AUD describing the evolution of his drinking said, *"I started drinking when I started working. I used to get tired after working for whole day so I would take a drink; or I would drink for the sake of enjoyment after getting my salary. It started in that fashion and gradually it became a habit. From enjoyment it got transformed to addiction"* (Male, 37 years). Another participant reported a similar story, *"Actually to tell you the truth I started drinking because I liked it but over time it became a habit. There was no reason as such (to start drinking), and I would drink for enjoyment. Then gradually my drinking at night went up"* (Male, 56 years).

5.3.2. Coping strategies

Men with AUD and SOs described a range of coping strategies to deal with their own or their family member's drinking problems. Some of these strategies are described below:

- i. Avoidance behaviours: Avoiding situations which and people who led to

drinking were reported as a self-help strategies by some men with AUD. These strategies included avoiding friends and social situations (e.g. parties) that encouraged drinking. *"I used to be at home, not going out of the house. Even if someone called me I would not go out. I used to avoid going to those friends (friends who, drink). After completing my work I used to come directly home"* (Male, 37 years). An alternative but related strategy used by one participant was to ask family members to accompany him whenever he attended social functions where alcohol could potentially be served. One man with AUD describing this strategy said the following: *"Even if I have to go to the market or function (social occasion) I would go with my wife. . ."* (Male, 48 years). Although men with AUD found these avoidance strategies helpful, they saw them as *"short-term"* solutions that were not always practical. Some of them also felt that such strategies would lead to them losing their friends.

- ii. Distraction: Many men with AUD used and some SOs encouraged a range of non-alcohol related recreational activities to take the drinker's mind off alcohol. Some examples of men with AUD distracting themselves are as follows: *"I do other things. . .keep myself busy.....like watching TV and playing with my children...."* (Male, 37 years), *"When I want to go away from alcohol I go out with my family.....for a family picnic or something"* (Male, 34 years). A SO reported doing the following to distract his son from drinking: *"We give him some work which he is interested in.....try to keep him engaged during his usual time (of drinking). . .we don't give him any outside work (chores which require leaving the house) in the evening"* (Female, 62 years, Mother).
- iii. Substitution: Men with AUD referred to commonly using aerated drinks or other non-alcoholic beverages as a substitute for alcohol to overcome cravings. *"I have to drink lot of soda, water, black tea. . . .in a day I have to drink around 7 to 8 lime sodas or simple soda (sparkling water) so that I don't feel any craving (for alcohol)"* (Male, 60 years).
- iv. Religious and spiritual strategies: Religious rituals and spirituality were found to be helpful strategies to manage drinking problems by men with

AUD as well as their SOs. Chanting, reading religious texts and attending religious activities in the temple like listening to discourses and participating in singing of bhajans (religious songs) were found to be helpful. Men with AUD used these strategies to distract themselves from cravings for alcohol. *"I used to continuously utter God's name till that feeling (craving) went away"* (Male, 65 years). *"For keeping the thoughts of drinking away, I read Bhagvad Gita (Religious text of Hindus)"* (Male, 52 years). Irrespective of religious background, prayer and religious rituals were seen by SOs to give hope and as a way of changing the drinking habits of their family members. A wife of a man with AUD said, *"I have tried a lot of religious things.....I pray to all the gods for him to improve. . .someone told me to fast on Saturday. I did that. . .but it didn't work. Someone told me to fast and give offerings to God on Thursdays during Margashirsh (holy month in Hindu calendar). I did that and I found some difference (reduction in drinking)"* (Female, 30 years, Spouse).

- v. Support from friends and family: Support from friends and family was reported to be helpful by some men with AUD, especially because they provided confiding relationships. One participant said, *"My brother is very understanding.....I go to him or call him each time I feel like drinking or have any other problem.....he never says anything bad to me. . .he gives me good advice"* (Male, 44 years).
- vi. Restricting access to alcohol: Restricting access to money to the family member with AUD was seen as an effective strategy by SOs and was also endorsed by some men with AUD. *"If he has excess money he spends it all on liquor.....so we give him the exact amount of money required for the thing to be bought"* (Female, 62 years, Mother). Reducing access to alcohol by changing geographical location was seen as a temporary measure to reduce alcohol consumption. *"He goes and stays at his sister's home for 2 days, and he is totally sober, stays away from it (alcohol) and after coming back here (home) he even swears that he won't drink alcohol again.....but here he has easy access to alcohol so he starts drinking again. . .but we can't keep him permanently at his sister's or other relative's house"* (Female, 37 years, Wife).

- vii. Anger management: Men with AUD occasionally reported anger management as a key strategy to control their drinking. One man said *“I started writing a daily diary about what I did in a whole day. If I feel bad or get angry, I write in that diary and tear that page and throw it in a dustbin. It helps me remove bad thoughts from my mind”* (Male, 38 years). Another man said: *“When I used to get angry, I counted up to 10 in my head; I don’t count them as 1, 2, 3 but backwards from 10 to reduce anger”* (Male, 44 years).

5.3.3 Health care providers and intervention settings

Men with AUD sought help from a variety of care providers and intervention settings. The first line of healthcare provision for these patients was formal HCPs in primary care, both in the public and the private sector. Men with AUD and their family members also sought help from non-formal care providers like religious healers, priests, and meditation and yoga therapists. If interventions provided by these providers were found to be ineffective then patients and their family members sought (or were referred to) specialist care from clinical psychologists, psychiatrists and residential detoxification and de-addiction centres. At a later stage, help was sought from the Alcoholics Anonymous (AA). Further details of these intervention settings and the non-pharmacological interventions that they provide are as follows:

i) Non-formal care providers and settings

Three main non-formal care providers were described. First are temples or churches with the priests as the care providers. Second, religious or spiritual organisations headed by a religious/spiritual healer, with structured intervention models that included prayer, practice of rituals, meditation and yoga. An example of such organisations is the ‘Brahmakumaris’ an organisation that claims to cause self-transformation through meditation and positive thinking. Another example of this model are religious/spiritual ‘Retreats’ in which one spends a definite period of time away from the normal routine of life for the purpose of reconnecting, usually through prayer, both with God and with oneself. Third meditation or yoga therapists, practicing specific systems of meditation and yoga independently or affiliated to centres such as the Art of Living, a non-governmental organisation engaged in stress-management and

social service initiatives.

All these care providers delivered a combination of some of the following psychosocial strategies: relaxation training, 'value education' (to reflect on and acquire attitudes and behaviour which are perceived to be effective for long term well-being), religious and spiritual strategies, meditation, physical exercise, psycho-education, focus on unconscious mechanisms, cognitive restructuring, and behavioural activation.

ii) Formal non-specialist care providers and settings

These include general physicians (GP), Ayurveda (system of Hindu traditional medicine with its origins in the Indian subcontinent in Vedic times) practitioners and Homeopathy (a system of alternative medicine) practitioners based in Primary Health Centres (PHCs), hospitals, non-governmental organisations or private clinics.

These HCPs delivered a range of psychosocial strategies as follows: psycho-education, personalised feedback, cognitive restructuring, behavioural activation, relaxation training, problem solving, meditation, religious/spiritual interventions, physical exercise, family psycho-education, and family counselling.

iii) Mental health specialist care providers and settings

This setting included psychiatrists, clinical psychologists, and social workers working in private practice or in mental health institutions such as university hospitals.

They usually practiced one or more of the following psychosocial intervention classes: Cognitive Behaviour Therapy (CBT), supportive psychotherapy, psychodynamic psychotherapy, Rational Emotive Behaviour Therapy (REBT), and Motivational Enhancement Therapy (MET). They primarily delivered the following psychosocial intervention strategies: psycho-education, MI, cognitive restructuring, behavioural activation, relaxation training, meditation, problem solving, focus on childhood experiences and unconscious mechanisms, family psycho-education and family counselling.

iv) 12 Step Facilitation (TSF) programmes

The various strategies that were reported to be used in TSF included psycho-education, addressing denial, mutual support, meditation, religious/spiritual support, cognitive restructuring, substitution with non alcoholic drinks or other activities, forgiveness, confession and behavioural activation.

v) Residential de-addiction centres

These centres provided individuals with social and vocational rehabilitation in individual and group format.

The primary psychosocial strategies employed included psycho-education, behavioural modelling, supportive counselling, MI, addressing denial, work therapy, physical activities, vocational training, social skills training, cognitive restructuring, behavioural activation, relaxation training, meditation, support groups, yoga, problem solving, focus on childhood experiences and unconscious mechanisms, family psycho-education and family counselling.

5.3.4 Psychosocial intervention strategies and techniques

Details of the strategies as delivered by the various practitioners are as follows:

i) Personalised feedback

Patients who had received treatment from formal care settings (PHCs, hospitals, in-patient and outpatient clinics, residential de-addiction centres) had received some variety of personalised feedback about their AUD problem. In the non-formal intervention settings, a type of personalised feedback was only offered by the Bramhakumaris.

The various steps reported in delivery of personalised feedback were assessment of current drinking patterns of the person with AUD, giving feedback about the specific risks associated with continued drinking, advising about the importance of changing current drinking patterns and recommending alternatives available for change. A practitioner said, *“I think that it (personalised feedback) engages the person. These people have never been spoken to about the use of alcohol apart from the blame that families place on*

them. It helps to change the focus from a very moralistic view to looking at the problem in a pragmatic manner. It gives people the optimism that they can change because you are telling them about the treatments and more importantly it links the alcohol use to the current problem" (Psychiatrist, Female, 42 years).

ii) Motivational Interviewing (MI)

Although most care providers encouraged their patients to enrol and adhere to treatment only a few specialists, such as psychiatrists and clinical psychologists, delivered structured MI.

Practitioners of MI considered resistance to change as a normal process, used a non-directive style, and supported self-efficacy. Those who used this approach also found it particularly effective in handling problems of denial. One practitioner of MI said, *"I use open ended questioning, reflection and affirmation which we find very useful not only while doing MI with people having alcohol problems but also as general therapeutic skills. The other thing that we use is a client centred approach which we find very useful, specially with patients who often come in or are brought in by concerned relatives but not necessarily very keen to do something about their drinking. This is called denial and MI provides tools to deal with such denial"* (Psychiatrist, Female, 42 years).

The various other techniques of MI reported by the practitioners included showing empathy, listening in a non-judgmental manner, conveying acceptance of the patient and also demonstrating discrepancies between the patients beliefs and behaviours. *"And then there are simple techniques.....I sit with the calculator and ask him what is your daily intake (of alcohol). If he says one bottle...it is Rs.100/-. So yearly it will be Rs 365,000/-, 10 years is Rs 33,65,000. So I ask the patient how much he could have saved (if he weren't drinking)? That means you could have built a house, and married off your daughter. And all this money is gone to waste and has destroyed your body. When you show this to them on the calculator the patients are stunned. They had never realized that they had spent so much money on alcohol"* (Social worker, Male, 39 years).

iii) Supportive counselling

Supportive counselling was predominantly offered by care providers operating out of in-patient and residential de-addiction centres. This basically included supporting the patient's actions in his efforts to control or quit alcohol, reassuring and instilling hope, and encouraging the patient to adhere to treatment.

iv) Psycho-education

Both formal and non-formal care providers used psycho-education as an intervention strategy. This involved promoting awareness and providing knowledge about alcohol addiction, treatment options, and the tools to manage, cope and live with alcohol use problems. All these components were delivered via oral instruction in groups or individual format through lectures and stories. *"So in that initial period for all the patients I take time to actually involve the patient and other family members and give some general information about the illness, medications and there are other things to tell the patients"* (Psychiatrist, Male, 54 years).

v) Cognitive restructuring

Almost all HCPs offered cognitive restructuring and its variations, both in formal and non-formal settings like Brahmakumaris, Art of Living, and spiritual/religious retreats.

Techniques used to identify irrational beliefs included questioning, challenging irrational thoughts, explanations using examples from persons' real life situations, and providing written material on self-help. *"What we do is that... we try to assess his faulty thoughts and irrational beliefs one by one. The patient keeps saying "I am good, I behave in the right way. I am not making any mistakes". But it can't be like this, this has to be explained to the patient...."unknowingly a mistake has happened through your hands. That you have to see for yourself and then you have to accept it". The second belief is "my family, my relatives should always behave properly towards me. They must take care of whatever I want. They should not behave against my wishes." Because of this stubbornness whenever people behave against his wishes, the patient becomes very frustrated. Then to lessen this mental restlessness, his dependence on the alcohol, increases. So he has to be explained about these*

beliefs ...and try to change his beliefs” (Bramhakumari, Female, 57 years).

vi) Problem solving

Problem-solving techniques were taught in outpatient clinics of general physicians, homeopathic doctors, psychologists, psychiatrists, residential de-addiction centres and Bramhakumari centres.

It involved activities designed to find solutions to the patients’ problems with the intention of imparting skills to him on how to approach and solve problems in a similar manner in the future. The care providers helped persons with AUD recognize day-to-day problems related to their alcohol use. Then they helped them to make a list of potential solutions to their problems, helped them choose the ones they found most promising and encouraged them to implement the solutions. These strategies were imparted through role-plays.

vii) Support groups

In addition to being an important strategy of treatment in residential de-addiction centres and in Alcoholic Anonymous groups, they were also used as a continuing care strategy by some formal health care providers. The different techniques used in support groups included accepting the problem, group discussion, listening and sharing of personal experiences concerning the problem, sobriety celebrations and use of prayers and mutual support to help one remain abstinent. One care provider who facilitates groups said, *“When a person wants to do anything, if you do it in a group it is much easier because they get strength from each other. When they share, they listen. Some of them would deny, others discuss. They also get social skills”* (Psychologist, Male, 46 years).

Another aspect of AA was the concept of ‘sponsor’, which was practiced by AA as part their 12-Step Facilitation programme. Persons with AUD were introduced to other individuals who were usually recovering or recovered ‘alcoholics’ and were referred to as a ‘sponsor’. The role of the sponsor was to strengthen the social network of the person with AUD through the development of a supportive relationship over time *“You should have a support network. You should have a sponsor to talk to. It is one of the five tools of AA relapse*

prevention. The sponsor is a senior recovered addict. Your sponsor will be your friend, philosopher and guide throughout the programme. Sponsor should be preferably a person who has undergone the process of alcohol recovery, so that he knows something about the recovery process” (GP, Male, 52 years).

Twelve Step Facilitation strategies were also used by specialist mental health care providers, by non-formal care providers such as Bramhakumaris and in residential de-addiction centres. They used techniques like affirmation, acceptance of the alcohol problem, forgiving self in spite of weaknesses or deficiencies and willingness to receive help for the problem to tackle denial in the patient.

viii) Religious and spiritual treatment ministrations

Various formal and non-formal care providers advised their patients to visit places of worship, listen to discourses by religious healers, seek forgiveness through prayers and rituals and participate in ‘bhajans’ (religious hymns) groups. Non-formal care providers also offered ‘value education’ to persons with AUD by referring to stories from religious works such as the Bible, Bhagvad Gita (spiritual book of Hindus) and Quran. *“We need to realize the importance of life. We need to take help of the spiritual aspect in our treatment. You know India has so many scriptures. So you tell him (patient) messages from the Bhagvad Gita or you tell them something from the Bible. You use whatever is needed at that time, whatever can transform him at that time, you use it” (Bramhakumari, Female, 57 years).*

ix) Vocational counselling

Vocational counselling was offered in one residential de-addiction centre. It entailed helping persons with AUD choose appropriate career options and teaching them vocational skills, *“We also give vocational rehabilitation to people with alcohol use...for three months...That is to those clients, who don’t have a job; you know there’s a gap in their work lives. They mainly inculcate discipline, of coming to work on time, working with other people, and getting into some kind of work ethic” (Social worker, Male, 38 years).*

x) Social skills training

HCPs offered social skills training to persons with AUD and also their family caregivers. It included teaching them to use appropriate skills to handle social situations in which there was an increased risk of drinking. The skills taught included assertiveness, drink refusal skills, and communication skills. Describing the skills taught to the patient with AUD, one practitioner said, *“All relevant areas are taken care of in 4 to 5 sessions. These include skills like assertiveness, time management, decision-making and problem solving. There are relationship skills as well as communication skills”* (Psychiatrist, Male, 54 years).

xi) Relaxation therapy and meditation

Mental health specialists, non-specialists and non formal care providers (for example, Bramhakumaris, Art of Living centres, and retreats) provided different forms of relaxation training such as breathing techniques, meditation, asanas (postural Yoga exercises), listening to religious songs and prayer, to help them attain a state of calmness, thus reducing stress and consequently reducing the craving for alcohol. Meditation was an important strategy in treatment offered by non-formal care providers (Brahmakumaris, Art of Living and Yoga). It was also encouraged or provided by some mental health specialists and one non-specialist care provider.

Two main forms (techniques) of meditation emerged from the IDIs, namely Raj Yoga and Art of Living meditation. Raj Yoga meditation included deep contemplation and spiritual understanding of oneself (*“self-realisation”*). Persons disconnected from their surroundings and their thoughts and through this process, attained positive energy and peace. Guided imagery was used to achieve this meditative state. *“When you practice Raj Yoga, you slowly become so relaxed and blissful that, whatever joy you were getting due to the alcohol you will getting through meditation so it acts as a replacement”* (Bramhakumari, Female, 57 years). The Art of Living mediation included removal of unwanted thoughts through deep silence, breathing exercises using different techniques such as Pranayama and Sudarshan Kriya and physical exercises (Yoga asanas). *“We have asanas which are more for the body. Of course, it has got the effect on the mind but asanas are more for the body. And breath, Pranayama, Sudharshan Chakra are for the mental balance. The definition of*

Yoga is union of the mind and the body. In such patients (people with AUD) the mind is in one place and the body is elsewhere. With Yoga we unite them. What happens to the body depends a lot on the mind" (Art of Living practitioner, Male, 41 years).

xii) Focus on past experiences and unconscious mechanisms

HCPs used this strategy to give insights and opportunities for change and emotional growth by exploring childhood experiences. They used techniques like assessment of and inquiry about childhood experiences, explaining the unconscious mechanisms leading to the drinking problems, and identifying any immature defence mechanisms and replacing them with mature defences. *"The base of all psychological problems exists in an individual's childhood and so I really try to find out what has happened in that individual's childhood"* (Psychologist, Male, 46 years).

xiii) Physical exercise

Almost all HCPs advised at least some form of physical activity or exercise to persons with AUD. *"When you are engaged in physical activity, there is selective concentration and also the secretion of adrenaline in the body. That leads to what is called runners high which is in turn a substitute for the craving for alcohol"* (GP, Male, 33 years).

Non-formal care providers often recommended use of Yoga asanas as a technique for physical exercise. *"Yoga postures comprises of 2 varieties, restorative postures and rejuvenating posture. These postures help alcoholic patients to exercise their hands and legs, and sleep and blood pressure are restored"* (Social worker, Male, 38 years). In residential de-addiction centres "therapeutic duties" and "work therapy" in the form of routine physical work (e.g. sweeping, cleaning, washing, digging, cutting wood etc.) were used as a means of physical activity.

xiv) Music Therapy

Music therapy was offered as an intervention strategy only in residential de-addiction centres. This basically entailed use of music in a skilled manner by a trained therapist to help patients relax and to facilitate the physical, emotional,

intellectual, and social recovery process, *"This effect (of music) is of two types. When we hear a taal (beats) it gives our brain energy whereas when we hear a sur (rhythm) it gives our brain relaxation. I do two things, I make them (patients) listen to music and I also encourage them to sing on their own"* (Psychologist, Female, 40 years).

xv) Addressing interpersonal issues with one's partner

This strategy involved the care provider facilitating communication between the person with AUD and his spouse through individual and combined sessions. Teaching the person with AUD and his spouse communication skills and problem solving skills were important components of this strategy. *"Many times what happens is that relationships (of the person with AUD) get spoiled. A lot of times what happens is that the addicted person does not talk with family members for long periods. If he (person with AUD) feels like talking with someone he goes out and talks with his friends. There is no communication in the house. There is no interaction amongst the people in the house. In one house they (husband and wife) stay as strangers. By giving therapy we try to bring about the right changes in the relationships of the couples. We try to solve the misunderstandings amongst them"* (Psychiatrist, Male, 54 years).

5.3.5 Desired outcomes

Men with AUD and their SOs wanted the following outcomes from treatment for the AUD:

i) Reduced intake of alcohol or abstinence and relapse prevention

All patients expressed a desire to quit or reduce their alcohol intake and this was perceived as one of their major goals from treatment, *"I want to stop it (drinking) completely... what else? If I drink a little then I will feel like drinking more and then I will become addicted again. So it is better to stop it completely no? I will have many benefits if I do that"* (Male, 60 years). While some men with AUD felt it absolutely necessary to totally stop drinking alcohol others wanted to reduce intake gradually over a period of time, *"I was never expecting any kind of miracle (with regard to improvement of drinking problems). Yes I want to further reduce my drinking. I'm not saying that I am going to stop*

completely; probably I will reduce my drinking to once a week, then once a month. Only drink at parties or some special occasions" (Male, 52 years).

Unlike some men with AUD who wished to reduce their drinking and not stop completely, the SOs were unanimous in their belief that the only goal of treatment should be total abstinence. *"I want him to stop drinking alcohol and then he should start working. There will be peace at home if he stops alcohol"* (Female, 30 years, Spouse). *"He should completely leave alcohol. Even if someone else is drinking in front of him then he should be able to refuse drinks"* (Female, 28 years, Spouse).

ii) Improved family relationships

For many men with AUD improving family relationships was the most important outcome. *"They (family) only have tension about me because I drink too much, otherwise they have no tensions. They say that they will give me whatever I want (to stop drinking). With them, if I am good they are happy about it. This is what I want to do"* (Male, 44 years). Men with AUD also spoke of wanting to change their drinking habits to bring happiness in the lives of their family members. *"I should recover from my drinking problems. If I am good (not drinking) then everything is good. Good in the sense that family is happy and wife is happy. She is facing problems because of my drinking"* (Male, 30 years).

SOs of men with AUD too aspired for improved family relationships. *"He (son) should stay well (not drink). He should meet our relatives! We don't have many relatives but he should maintain contact at least with the few relatives we have! We want him to improve relationships with our family members"* (Female, 62 years, Mother).

iii) Improved occupational functioning

Some men with AUD alluded to their revived occupational functioning bringing happiness both to themselves and to their families, *"I took the advice of the counsellor and worked towards reducing my alcohol intake. After two years without a job, I got a job. Getting a job is actually a major relief. Before my drinking problem started I never used to be without any money in my pocket. Now I am never ashamed to go out with my son as I can buy him whatever he*

wants. My wife also has reduced her nagging (after reducing alcohol intake)" (Male, 52 years). Another man with AUD too stressed the value of keeping oneself busy through work and said, *"Work seriously, keeps you occupied, don't be idle at any time and make time to attend AA meetings which will keep you alive and in touch with all things"* (Male, 65 years).

SOs too stressed on the importance of the man with AUD getting a good job. *"I want him to stop his drinking. I also want him to get nice job as he is having problems in riding the bike (his current job was ferrying passengers around on a motorbike). He has injury of the back, his hands tremble, and his stomach hurts. If he gets a different job then everything will be fine"* (Female, 43 years, Spouse).

iv) Improved emotional and physical wellbeing

Men with AUD recalled how their physical and emotional conditions improved once they started treatment and reduced their alcohol intake. Describing how his life changed after joining AA, one man said, *"I had to drink in the morning, I had to drink in the night. If there was a party, I had to go and drink. After joining AA I feel no tension at all. I feel nice now"* (Male, 65 years). Another man with AUD spoke of how his affiliation to a spiritual group had a positive effect on him, *"I joined Bramhakumari and did the seven day course. I found meaning in my life. I started reducing my drinking. No one told me. In my mind I decided, one week half peg, second week half peg and by doing that I was able to stop drinking in three months. My life is completely changed now. Now I experience happiness, peace, and love"* (Male, 52 years).

Men with AUD were also aware of the impact of alcohol on their physical health and spoke of improved physical health as an added benefit of giving up alcohol. *"Now I have taken these tablets and I have been alright now. I have a good appetite. When I was drinking I would not feel hungry because my stomach would be full of alcohol. I don't want to have liver problems; I don't want to have health problems. But if I start drinking again, then I will definitely have drinking problems"* (Male, 44 years). SOs too agreed that successful treatment of AUD led to improved physical health. *"Treatment helped him a lot. His physical problems like giddiness, lack of appetite, lethargy to work and falling sick often;*

all these complaints have stopped” (Female, 28 years, Spouse).

5.3.6 Desired treatment

i) Characteristics of delivery agent

Many men with AUD and SOs stressed on the importance of being treated with empathy by HCPs and being given appropriate guidance. One man with AUD said, *“The counsellor should have good knowledge and understand our problems and opinions. I have only one expectation from the counsellor and doctor. They should guide us properly without getting angry, they should understand our situation and the issues that affect us, and guide us properly”* (Male, 45 years). The ready availability of the person delivering the treatment was seen to be of paramount importance. One man with AUD said, *“For me, whenever I require to talk to the counsellor I should be able to give him a call and go and meet him. I was going to a counsellor and she taught me skills on how to reduce alcohol intake and how to avoid triggering situations. I have reduced my drinking now”* (Male, 56 years). Similarly another man with AUD stressed the importance of having the contact number of the counsellor so that he could be easily contacted in time of need. *“Wherever the counsellor is, whether he is at the Centre or he is at his home (he should be contactable) ...you just call him up and tell him so and so is the problem; what should I do?take his advice”* (Male, 37 years).

ii) Characteristics of the treatment

The importance of psychosocial interventions was acknowledged by a man with AUD who said *“Counselling is very much needed till a person becomes psychologically ready; merely medicines will not benefit him”* (Male, 56 years). Learning from other people’s experiences was seen to be an important aspect of treatment. One man attending AA said, *“And my turning point came only after I attended this meeting (AA). Talking with another alcoholic will save you from drinking. When somebody was sharing his mess, it felt like my own story and I started changing”* (Male, 65 years). A SO spoke of the importance of the motivation and internal desire to change in treatment for AUD. *“Doctor’s treatment by itself doesn’t have any effect on you because if you are not willing*

to change then those medicines do not show effect on the person. The doctor says that if the individual does not cooperate, he will not become better" (Female, 28 years, Spouse).

iii) Location of treatment

There was wide variation in opinions on where the treatment for AUD should be delivered. Some participants did not regard the place of treatment as an important factor to seeking care, a few however said, for moderate drinkers the distance of the treatment centre did not matter but for heavy drinkers this would be an important aspect as treatment should be available close to home. *"If someone has less severe alcohol problem, than he can come to a place (for treatment) that requires some travel. If he has a serious problem, then the treatment needs to happen at a nearby place"* (Male, 65 years). Issues like cost of travel and stigma were other considerations when deciding where the treatment was delivered. One participant from a village said, *"I feel these methods of treatments should be provided in the city. If these methods of treatment are given in the village the person will not take it up. He will be worried that someone (from the village) will see him. Therefore these methods of treatment should be far away from the village so that the person can go fearlessly and take these treatments"* (Male, 38 years). On the other hand another participant who believed that the treatment should be delivered closer to home said, *"It would be better if this treatment is available in our hometown because treatment causes extra expenses like travel expenses. If the treatment is nearer to home then it would save that money"* (Female, 37 years, Spouse).

iv) Involvement of significant others in treatment

Almost all men with AUD agreed on the importance and the benefit of the role played by SOs (family and friends) in treatment. They appreciated the concern and support of their family and friends and valued the initiative taken by them in seeking appropriate care for them. They also suggested that family should be involved in their treatment, as it served to encourage them further, *"According to me, family members should help. When the wife or parents come with us for treatment, we get the encouragement that someone is there to support us and even they learn something from here (Treatment centre)"* (Male, 34 years).

Family support was expected in the form of taking their relative with AUD to AA meetings, trying to understand their problems and behaviour and helping them in relapse prevention. *“Only thing I told him (my brother) was to phone me. If I had craving at that time and he calls me at that time then I am not going to drink. He phones me every day and reminds me”* (Male, 44 years).

Another perspective presented by one participant was that, sometimes, family members only served to aggravate the problem of drinking because of their poor understanding of their relative’s psyche. However he also added that the family’s involvement in treatment was important by saying, *“Family members should be trained in this, should understand what this person’s (person with AUD) psychology is, what he is feeling. The family should be told frankly that the problem has aggravated because of them too”* (Male, 60 years). One man with AUD was very clear in his belief that his cure rested in the hands of specialists and his family would not be able to help him in this regard. He said, *“I don’t think my family members will be able to cure me or give me solutions because the doctor is the best person to cure something. For alcoholism, treatment can be only in places like Kripa Foundation (Rehabilitation centre). Medication helps if it is given properly. The main thing is believing that God will help, find solutions to your problems and have a counsellor whom you can ring up anytime and take help wherever he is”* (Male, 37 years).

5.4 Output

There are several implications of the findings from this qualitative study, some proximal and others distal in the intervention development process. The proximal utility of the findings are that they helped identify a) psychosocial strategies that are being used by formal and non formal practitioners in the setting for which the new psychosocial intervention is being developed, b) the desired outcomes of patients with AUD and their family members, and c) the coping strategies that are being used by patients with AUD and their family members. This was a critical step in the treatment development process as it was the first step in which data was directly collected from the setting for which the intervention was being developed. Data from all three sets of participants was crucial and equally important. It was crucial, independently for each set of participants but also more informative when triangulated with each other.

Identification of psychosocial strategies that are already being used in the setting provided an indirect evidence of their acceptability to the recipients in that setting. Some of these were also supported by evidence from the international and/or local reviews (e.g. problem solving, personalised feedback). Similarly, the identification of coping strategies that patients with AUD and their family members were using successfully helped to contextually support the evidence for psychosocial strategies for which there was existing evidence of effectiveness/impact from the international and/or local evidence, e.g. managing friends and situations which promote drinking. Finally, identification of perceived causal pathways for development of AUD helped identify issues which would need to be addressed in the psychosocial intervention being developed e.g. interpersonal stressors were seen as important contributors to developing and maintaining AUD. Table 5.3 maps the psychosocial strategies being used by the various HCPs, and coping strategies used by patients with AUD and their significant others on to the international and local evidence on the effectiveness/impact of psychosocial strategies for AUD. Some of the findings from this qualitative study that would be of use in the distal stages of the intervention development process include those related to the 'desired outcomes' and 'desired treatments'. For example the tension between reduced intake of alcohol or abstinence as intervention goals would have to be explored further and appropriate flexibility to allow for both these options would have to be built into the new intervention. Similarly, the opinions expressed about characteristics of the counsellor would have to be taken in consideration while recruiting and training the counsellors to deliver the new intervention.

However, the focus at this stage of the intervention development process is on the proximal utility of the findings. All the psychosocial strategies identified until now (Table 5.3) with international and/or contextual evidence will now progress to the next stage (Chapter 6) where these will be filtered based on perceived effectiveness, and safety and feasibility of delivery by lay counsellors.

Table 5.3: Psychosocial strategies derived from the various steps of the intervention development process

INTERVENTION STRATEGY	SOURCE					
	mhGAP	LITERATURE REVIEW			IN DEPTH INTERVIEWS	
		International	Local	Strategies that could be potentially helpful based on findings from the Explanatory Models review	Delivered by HCPs	Felt need or coping strategy used by patients and/or SOs
Personalised feedback		✓	✓		✓	
Motivational interviewing	✓	✓	✓		✓	
Psycho-education			✓	To tackle lack of awareness about alcohol problems and availability of interventions.	✓	
Supportive counselling			✓		✓	
Cognitive restructuring	✓	✓	✓		✓	
Problem solving			✓		✓	Financial problems seen as causal factor.
Enlisting social support			✓			Support from friends and family was reported to be an effective coping strategy.

INTERVENTION STRATEGY	SOURCE					
	mhGAP	LITERATURE REVIEW			IN DEPTH INTERVIEWS	
		International	Local	Strategies that could be potentially helpful based on findings from the Explanatory Models review	Delivered by HCPs	Felt need or coping strategy used by patients and/or SOs
Support groups			✓		✓	
Vocational counselling					✓	
Relapse prevention			✓	To manage 'external situations, euphoric states and unpleasant mood states which were seen as triggers for relapse'		Distraction and substitution with non-alcoholic drinks were used as coping strategies to avoid drinking.
Social skills training			✓		✓	Peer pressure seen as causal. Managing friends and situations that promote drinking were used as coping strategies.

INTERVENTION STRATEGY	SOURCE					
	mhGAP	LITERATURE REVIEW			IN DEPTH INTERVIEWS	
		International	Local	Strategies that could be potentially helpful based on findings from the Explanatory Models review	Delivered by HCPs	Felt need or coping strategy used by patients and/or SOs
Family psycho-education			✓			
Family counselling			✓			Impact on family relationships. Interpersonal stressors seen as causal.
Relaxation				For stress management	✓	Psychosocial stress was seen as an important causal factor.
Geographical cure						Reducing access to alcohol by staying away from home was found to be effective.
Physical exercise					✓	
Religious and spiritual practises			✓		✓	Religious/spiritual activities were seen as effective coping strategies.
Addressing unconscious mechanisms					✓	

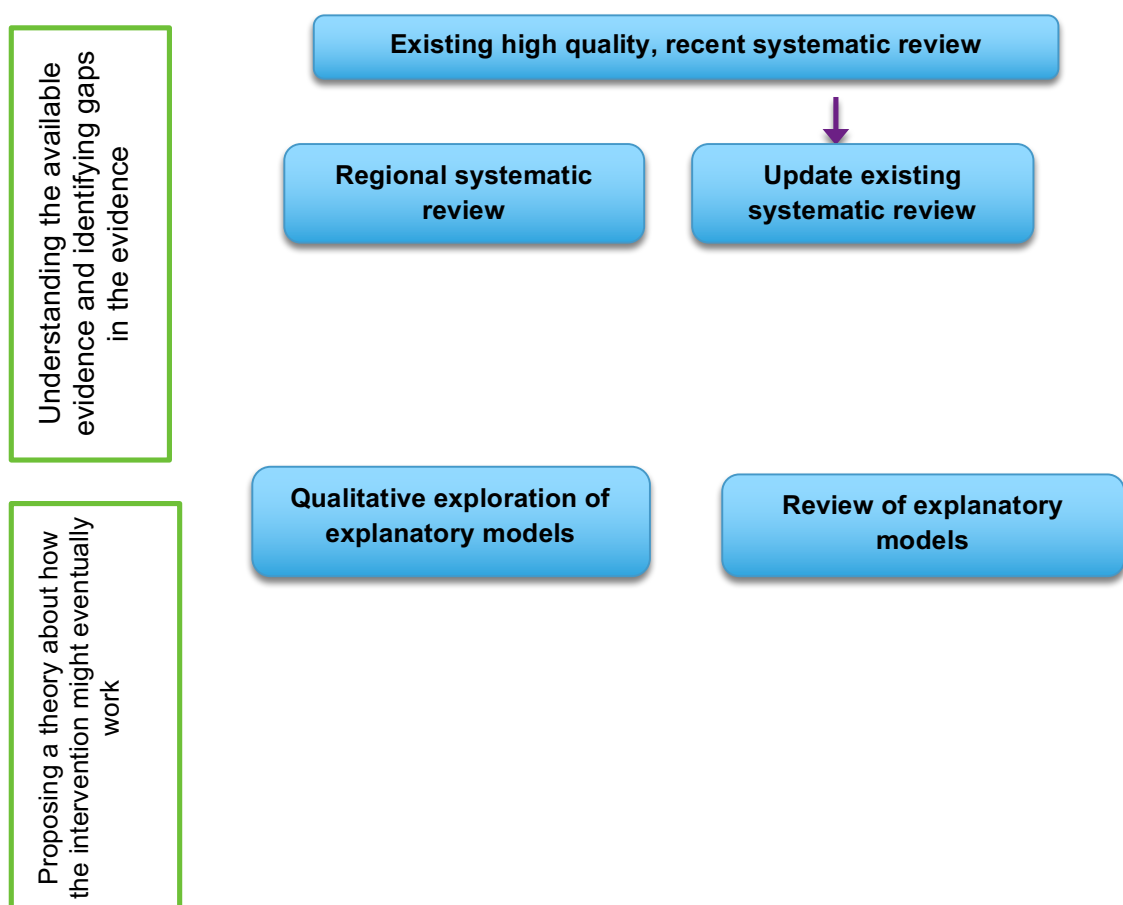
INTERVENTION STRATEGY	SOURCE					
	mhGAP	LITERATURE REVIEW			IN DEPTH INTERVIEWS	
		International	Local	Strategies that could be potentially helpful based on findings from the Explanatory Models review	Delivered by HCPs	Felt need or coping strategy used by patients and/or SOs
Addressing interpersonal issues with one's partner			✓		✓	Impact on family relationships. Interpersonal stressors seen as causal.
Focus on past experiences and relationships					✓	
Music therapy					✓	

Chapter 6 Survey of Mental Health Experts and Non Specialist Health Workers^{††}

6.1 Background

Through the preceding steps a list of psychosocial intervention strategies that fulfilled one or more of the following characteristics was generated: a) Evidence of effectiveness from international literature; b) Evidence of impact from local literature; c) Supported by a literature review of regional explanatory models; d) Supported by local explanatory models and coping strategies; and e) Reported to be used by local service delivery agents (Figure 6.1). It is important to note that although the preceding steps have been described sequentially they were actually conducted in parallel i.e. all the three systematic reviews and the qualitative studies happened more or less at the same time. However, from this point onward all the steps followed a sequential path.

Figure 6.1: Progress of the intervention development process



^{††} Author contribution to the methods: I analysed the data, synthesised the results, and interpreted the findings.

The rationale and design of these steps made certain assumptions about this list of psychosocial intervention strategies. The assumptions were that these strategies would be acceptable to the delivery agents i.e. non-specialist health workers (NSHW) and recipients (patients and their SOs), and feasible and safe to be delivered by NSHW in low resource settings in a low and middle income country (LMIC) like India. These assumptions were based on the fact that these strategies were derived from or supported by contextual evidence derived from local literature and from interviews done with various stakeholders from in India. To make the process more rigorous and to further validate it, it was decided to introduce a step in the process that would further refine the list of psychosocial strategies based on input from stakeholders who actually delivered (mental health specialists) or would deliver (NSHW) these psychosocial strategies.

The aim of this step was to identify psychosocial strategies that would be most feasible and safe for delivery by NSHW and acceptable to patients in the Indian context.

6.2 Methods

6.2.1 Study design

A cross sectional survey was conducted with two groups of participants as described below.

6.2.2 Sampling strategy

The sampling strategy was a combination of convenience sampling and maximum variation sampling. However, sample size calculations were not done as we were not testing a hypothesis and were conducting an exploratory study.

Convenience sampling, a type of non-probability sampling method, selects a sample from a population that is conveniently available to participate in study and easy to access. Such a sampling technique is effective during exploratory stages of a research project. Some advantages of convenience sampling include its simplicity, utility in pilot studies, facilitation of data collection in a short period of time, and low cost to implement. However, this sampling strategy also has disadvantages and these include high vulnerability to selection bias, unclear generalisability, and high probability of sampling error.

Participants were selected using maximum variation sampling (Marshall, 1996), a type of purposive sampling strategy that aims for representativeness by including a wide range of extremes rather than through equal probabilities. The advantage of such sampling is that it allows the researcher to get a richer and more authentic representation of the phenomenon under study. The risk in maximum variation sampling is the reduced generalisability and that the diversity in the sample will in turn lead to extreme diversity in responses and this will make it difficult to describe a coherent story.

6.2.3 Sample

The participants in the survey included 1) mental health professionals, and 2) NSHW.

The mental health professionals were defined as persons with known or demonstrable experience and expertise in the field of mental health care. The maximum variation was achieved by selecting mental health professionals from various parts of India and from a range of professional disciplines working in the field of mental health viz psychiatrists, clinical psychologists, and psychiatric social workers. In India, there are no clearly defined streams of training in addictions medicine/addictions mental health/addictions psychiatry (except in a very limited number of tertiary care institutions). Most general mental health professionals deal with and manage patients with alcohol use disorders as a part of their generalist mental health practice. We recruited such generalist mental health practitioners to reflect the contextual reality. The NSHWs were represented by lay or community health workers in existing public health programmes and did not have any professional qualifications in mental health care. The NSHWs were recruited from the two PREMIUM sites (Goa and Satara, India) and the maximum variation was achieved through adequate representation of both genders and a range of different professional categories of NSHWs. This study was a part of formative research and was not designed to test any hypothesis. Hence we did not conduct any formal sample size calculations. The sample was selected to ensure maximum variability with regard to professional group, years of experience, gender, age and location within India.

6.2.4 Data collection

The survey questionnaire listed all the strategies (with definitions) that were identified in the previous steps of this study (i.e. systematic reviews and IDIs)

Box 6.1: Definitions of dimensions on which psychosocial strategies were rated

Acceptability: Patient easily receives strategy as suitable within Indian cultural context.

Feasibility: Possible for NSHW with appropriate training and supervision to deliver.

Effectiveness: Strategy brings about an observable and expected change.

Risk of harm: Involves potential for harm if delivered by NSHW.

and the participants were asked to rate each strategy on a five point Likert scale on the following four dimensions: 1) Feasibility of delivery by a NSHW who receives appropriate training and supervision; 2) Acceptability to patients in the Indian cultural context; 3) Perceived effectiveness of the strategy to bring about an observable change in the symptoms and signs of the disorder; and 4) Risk of harm posed by a NSHW delivering this strategy. A definition of each of these four dimensions was provided to aid the participants with the rating (Box 6.1).

The participants had to rate each of the strategies on these four dimensions using a five point Likert scale where '1' denoted 'low probability' and '5' denoted 'high probability'. For the 'Risk of harm' parameter, the scale remained the same (i.e. Likert of 1 to 5) but the interpretation of the rating changed for obvious reasons i.e. '1' meant 'low probability of harm' (or 'most safe') and '5' meant high probability of harm ('least safe'). The questionnaire was then piloted with four mental health professionals and four NSHWs to test its design, content, difficulty level, ease to complete and language. The final questionnaire was developed based on the suggestions made by the participants in the pilot. For the NSHWs at the Satara site, the questionnaire was translated in Marathi (local vernacular) and the English language versions were used for all the mental health professionals and NSHWs from Goa (Appendix 4). The questionnaire was emailed to all the mental health professionals. For the NSHWs the questionnaire was administered individually over the phone or face to face individually.

6.2.5 Data Analysis

Data was entered in MS Excel. If a participant had not checked the rating box for any dimension or checked more than one boxes for a single dimension then these were treated as missing values. The MS Excel database was then converted and imported to STATA. An overall (combining the following dimensions: perceived effectiveness, acceptability and feasibility) mean score was calculated separately for the two participant groups. An overall mean combining the mean scores of both participant groups was computed. The risk of harm scores were recoded as follows: 1 was recoded as 5, 2 as 4, 4 as 2 and 5 as 1 and mean was calculated together for both the participant groups. After recoding, the interpretation of the scores for risk of harm changed with 5 indicating low risk of harm and 1 indicating high risk of harm.

An a priori decision was made by the investigators' group to select strategies with a low risk of perceived harm when delivered by lay counsellors (Mean scores ≥ 4) and a high composite score for acceptability, feasibility and effectiveness (Mean scores ≥ 3), which would then be utilised in the next step of the intervention development process. A higher threshold for safety was set because one of the more important considerations for an intervention delivered by NSHWs is its safety. The overall scoring system and thresholds for selection were based on discussion and consensus within the investigators' group. Thus, although there was no empirical evidence in support of the system, it was based on the collective clinical and research experience of the investigators' group.

6.3 Results

~~72 participants (26 mental health professionals and 46 NSHWs) were invited for the survey. 58 (80.6%) completed the questionnaire. 15 (57.7%) mental health professionals and 43 (93.5%) NSHWs.~~ 72 participants were invited for the survey and 58 (80.6%) completed the questionnaire. More specifically, of the 26 mental health professionals that were invited, 15 (57.7%) completed the questionnaire and of the 46 NSHWs invited, 43 (93.5%) completed the interview. A majority of the mental health professionals were psychiatrists, males, had more than 20 years of professional experience and lived in South India. A majority of the NSHWs were health counsellors, females, and had less than 10 years of professional experience. Details are presented in Table 6.1.

Table 6.1: Socio-demographic profile of participants in the survey

	Mental Health Professionals (n=15) n (%)		Lay Counsellors (n=43) n (%)	
Type	Psychiatrist	10 (66.7)	Health Counsellors ¹	11 (25.6)
	Clinical Psychologist	3 (20)	Health Assistants ²	4 (9.3)
	Psychiatric Social Worker	2 (13.3)	Hospital ward attendants ³	8 (18.6)
			Accredited Social Health Activist ⁴	8 (18.6)
			Multi-purpose health workers ⁵	7 (16.3)
			School Counsellors ⁶	5 (11.6)
Experience				
Up to 10 years		4 (26.7)		35 (81.4)
11-20 years		5 (33.3)		4 (9.3)
>20 years		6 (40)		4 (9.3)
Location	North India	3 (20)	Goa	21 (48.8)
	East India	2 (13.3)	Satara	22 (51.2)
	West India	4 (26.7)		
	South India	6 (40)		

	Mental Health Professionals (n=15) n (%)		Lay Counsellors (n=43) n (%)	
Female gender	6 (40)		33 (76.7)	
Age (in years)	30-39	5 (33.3)	20-29	17 (39.5)
	40-49	5 (33.3)	30-39	15 (34.9)
	50-59	5 (33.3)	40-49	11 (25.6)

¹Attended a short counselling course and provides basic counselling.

²Works in community settings under the guidance of a qualified healthcare professional (e.g. nurse), generally assisting with patients' overall comfort.

³Works in hospital settings under the guidance of a qualified healthcare professional (e.g. nurse), generally assisting with patients' overall comfort.

⁴Local women trained to work as health educators and promoters in their communities.

⁵Grass root health functionary for the control of communicable diseases.

⁶School based psychologists who play a role in helping children deal with the issues that cause emotional distress.

Table 6.2 describes the results of the survey. The mean composite score (acceptability, feasibility and perceived effectiveness) by mental health professionals for the various strategies ranged from 2.3 (Addressing unconscious mechanisms) to 4 (Family psycho-education). The mean composite score (acceptability, feasibility and perceived effectiveness) by NSHWs for the various strategies ranged from 3.1 (geographical cure) to 3.7 (relaxation, physical exercise). The overall (mental health professionals and lay counsellors) mean composite score (acceptability, feasibility and perceived effectiveness) ranged from 3.1 (focus on past experiences and relationships, addressing unconscious mechanisms) to 3.8 (physical exercise). The mean score for perceived safety ranged from 1.2 (addressing unconscious mechanisms) to 4.7 (physical exercise).

For the scores given by the mental health professionals, except for cognitive restructuring, focus on past experiences and relationships, and addressing unconscious mechanisms, all other psychosocial strategies had a mean of ≥ 3 . For the scores given by NSHWs, all the strategies scored ≥ 3 . For the mean of the aggregate scores by the mental health professionals and NSHWs, except for addressing unconscious mechanisms, all of the other psychosocial strategies scored ≥ 3 . Based on the combined rating of mental health professionals and NSHWs, music therapy, religious/spiritual practices, focus on past experiences and relationships, addressing unconscious mechanisms and addressing interpersonal issues with one's partner were deemed to be unsafe (Mean score < 4) to be delivered by NSHWs.

The strategies were then rated using an a priori determined rating scheme as follows: '++' for a composite score of both mental health professionals AND lay counsellors ≥ 3 AND mean risk of harm score ≥ 4 indicating high acceptability, feasibility, perceived effectiveness and safety; '+' for a composite score of either mental health professionals OR lay counsellors ≥ 3 AND risk of harm score ≥ 4 indicating moderate acceptability, feasibility, and perceived effectiveness and high safety; and '-' for risk of harm score < 4 indicating moderate to low safety even if the strategy was perceived as acceptable feasible and safe (composite score ≥ 3). Based on this rating scheme, except for religious and spiritual practices, addressing unconscious mechanisms, addressing interpersonal issues with one's partner, focus on past experiences and relationships, and

music therapy, all other strategies were perceived to be acceptable, feasible, effective and safe to be delivered by lay counsellors (Table 6.2).

Table 6.2: Rating of psychosocial ratings on acceptability, feasibility, perceived effectiveness and safety

Intervention strategy	Acceptability, feasibility, and perceived effectiveness			Mean score for perceived safety	Perceived acceptability, feasibility, effectiveness and safety
	Mean score by mental health professionals	Mean score by lay counsellors	Mean composite score		
Psycho-education	3.9	3.3	3.5	4.1	++
Personalised Feedback	3.3	3.2	3.2	4.0	++
Motivational Interviewing	3.3	3.4	3.4	4.1	++
Problem solving	3.3	3.5	3.4	4.3	++
Relapse prevention	3.2	3.3	3.3	4.2	++
Supportive counselling	3.7	3.4	3.5	4.3	++
Enlisting social supports	3.6	3.5	3.5	4.3	++
Social skills training	3.4	3.5	3.5	4.4	++
Vocational counselling	3.5	3.6	3.5	4.4	++

Intervention strategy	Acceptability, feasibility, and perceived effectiveness			Mean score for perceived safety	Perceived acceptability, feasibility, effectiveness and safety
	Mean score by mental health professionals	Mean score by lay counsellors	Mean composite score		
Cognitive restructuring	2.6	3.4	3.0	4.3	+
Geographical cure	3.5	3.1	3.3	4.2	++
Music therapy	3.0	3.2	3.1	3.5	-
Religious/spiritual practices	3.5	3.3	3.4	3.9	-
Relaxation	3.6	3.7	3.7	4.6	++
Physical exercise	3.9	3.7	3.8	4.7	++
Focus on past experiences and relationships	2.6	3.3	3.0	3.8	-
Addressing unconscious mechanisms	2.3	3.4	2.8	1.2	-
Family psycho-education	4.0	3.5	3.7	4.4	++

Intervention strategy	Acceptability, feasibility, and perceived effectiveness			Mean score for perceived safety	Perceived acceptability, feasibility, effectiveness and safety
	Mean score by mental health professionals	Mean score by lay counsellors	Mean composite score		
Family counselling	3.9	3.5	3.7	4.4	++
Addressing interpersonal issues with one's partner	3.4	3.5	3.5	3.8	-
Support groups	3.8	3.6	3.7	4.5	++

6.4 Output

All the previous steps before the survey of mental health professionals and NSHWs were designed with the aim of identifying and elaborating psychosocial strategies for harmful drinking which had international and local evidence for effectiveness some of which were supported by contextual evidence gathered through the review of explanatory models and in depth interviews with various stakeholders in the settings in which the intervention would eventually be delivered. Thus, these steps generated a list of psychosocial strategies for harmful drinking which were effective and potentially suitable for delivery by NSHWs in the Indian setting. This survey was designed to use the experience of mental health professionals and NSHWs working in Indian settings to then filter these psychosocial strategies to narrow down this list further to those strategies which were perceived to be effective, feasible, acceptable and, most importantly, safe when delivered by NSHWs in the Indian setting. Based on the survey 16 out of the original 21 psychosocial strategies met those criteria. These psychosocial strategies were then taken forward to the next step of the intervention development process where they were put together into a credible psychosocial intervention backed by a theoretical framework. Table 6.3 lists all the psychosocial strategies, their source step and the outcome of the survey.

The following strategies were dropped out at this stage: Religious and spiritual practises, addressing unconscious mechanisms, addressing interpersonal issues with one's partner, focus on past experiences and relationships, and music therapy. They were primarily perceived to be unsafe to be delivered by NSHWs. Although, the methodology used in the survey does not allow us to examine the reasons why these strategies were perceived to be unsafe when delivered by NSHWs, one could speculate on the reasons. All the strategies that were deemed to be unsafe are the ones that would require a substantive level of training and expertise to deliver and if delivered inappropriately by non-specialists with inadequate expertise they had the potential of causing more harm than good.

There are several limitations to the methodology that we followed. These include the use of a scoring system that did not have any empirical support and

the participants who might not have direct experience of the psychosocial strategies that they were asked to rate. Although the mental health professionals sampled for the survey were not 'addictions specialists' as defined in the Western context, in Indian settings, except in centres of excellence, there are generally no trained 'addictions specialists'. In Indian general mental health professionals deal with patients having addictions and hence come the closest to 'addictions specialists' in terms of experience. The outcome of these limitations could be the inappropriate selection of some strategies that are too sophisticated for lay counsellors to deliver e.g. cognitive restructuring. However, one of the strengths of this treatment development process is that the selection of a psychosocial strategy does not happen in isolation based purely on the data from a single step. The checks and balances built into the system allow the addition or removal of strategies at subsequent steps based on triangulation of new data (as will be seen in the subsequent chapter where psychosocial strategies selected at this stage get excluded).

Table 6.3: Psychosocial strategies identified in the previous steps, their source step and the outcome of the survey

INTERVENTION STRATEGY	SOURCE				
	LITERATURE REVIEW			IN DEPTH INTERVIEWS	SURVEY
	International	Regional	Explanatory Models		
Personalised feedback	✓	✓		✓	++
Motivational interviewing	✓	✓		✓	++
Psycho-education	✓	✓	✓	✓	++
Supportive counselling	✓	✓		✓	++
Cognitive restructuring	✓	✓		✓	+
Problem solving	✓	✓		✓	++
Enlisting social support	✓	✓		✓	++
Support groups	✓	✓		✓	++
Vocational counselling	✓			✓	++
Relapse prevention	✓	✓	✓	✓	++
Social skills training	✓	✓		✓	++
Family psycho-education	✓	✓			++
Family counselling	✓	✓		✓	++
Relaxation	✓		✓	✓	++
Geographical cure				✓	++
Physical exercise				✓	++

INTERVENTION STRATEGY	SOURCE				
	LITERATURE REVIEW			IN DEPTH INTERVIEWS	SURVEY
	International	Regional	Explanatory Models		
Religious and spiritual practises	✓	✓		✓	-
Addressing unconscious mechanisms				✓	-
Addressing interpersonal issues with one's partner	✓	✓		✓	-
Focus on past experiences and relationships	✓			✓	-
Music therapy				✓	-

Chapter 7: Developing a theoretical intervention framework^{‡‡}

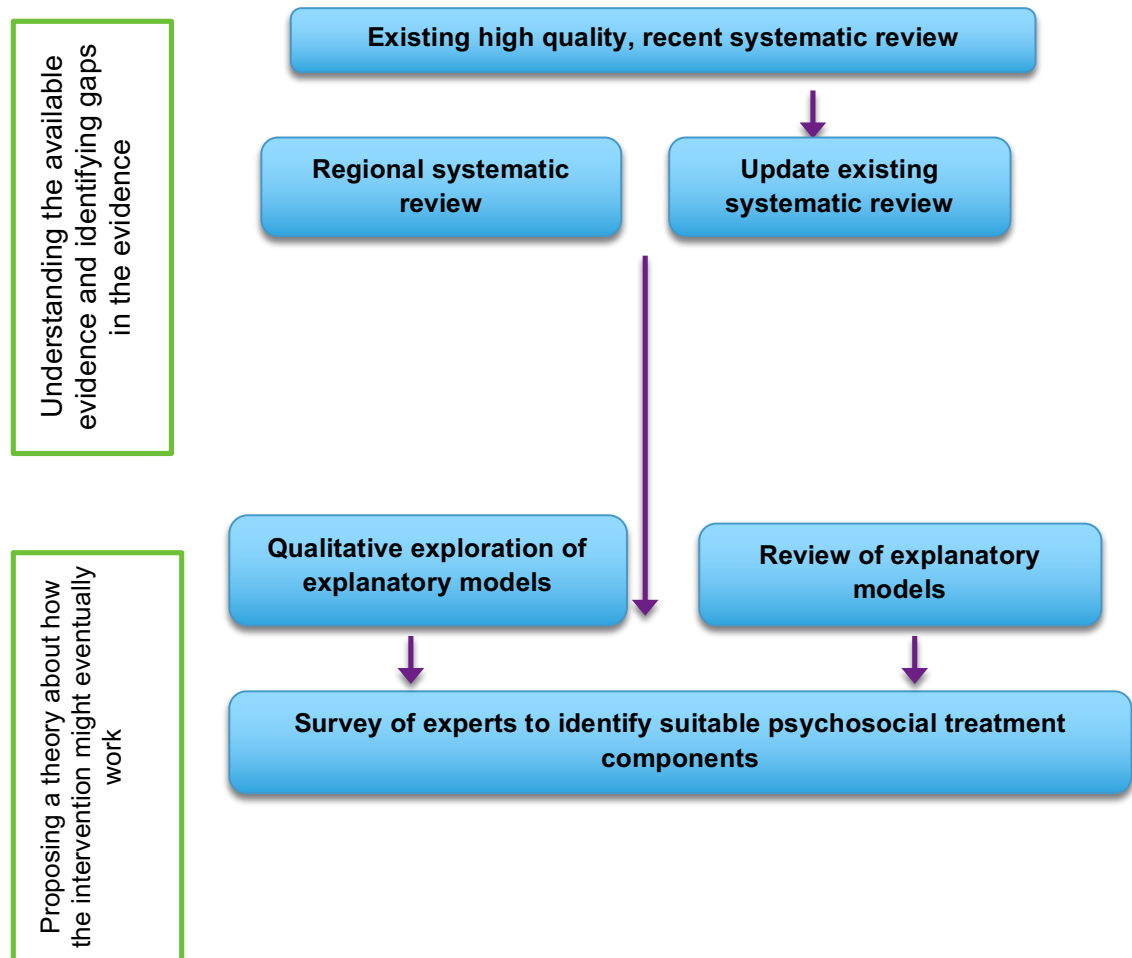
7.1 Background

At the end of the previous step we had a list of psychosocial intervention strategies which were evidence based (derived from the international and local review of interventions for Alcohol Use Disorders [AUD]), contextually appropriate (informed by literature review of explanatory models of AUD and in-depth interviews [IDI] of men with AUD, their significant others [SO] and healthcare providers) and perceived to be effective, acceptable, feasible and safe (according to the survey of mental health professionals and non-specialist health workers [NSHW]) (Figure 7.1). The next step was to develop a theoretical model of the new contextually appropriate intervention using these component psychosocial strategies to develop a psychosocial intervention for harmful drinkers to be delivered by NSHWs in primary care.

Prior to the evaluation of an intervention it is important to model it as it helps to gain a better understanding of how it works (for example, through the independent and interactive effects of each component) and its possible effects (for example, intermediate and final outcomes). Modelling also helps to identify possible weaknesses in the intervention pathway, which in turn inform refinements in the intervention. There is no one method for modelling a treatment and the decision should be based on the particular requirements of the intervention development project. Some modelling methods suggested by the MRC include the use of computer simulations, economic modelling, qualitative testing through focus groups, preliminary surveys, case studies, or small observational studies (Campbell et al., 2000).

^{‡‡} Author contribution to the methods: I contributed to the development of the interview guides, I co-facilitated the group work and Focus Group Discussions at the Treatment Development Workshops, analysed the data, synthesised the results, and interpreted the findings.

Figure 7.1: Progress of the intervention development process



For the modelling of the intervention we were developing we conducted treatment development workshops that used qualitative research methods to assemble and iteratively refine the psychosocial intervention package. The aims of these treatment development workshops were to a) refine the list of strategies identified for treating AUD, and organise/schedule them to form a coherent psychosocial intervention and map phases of intervention delivery, and b) understand the barriers to delivering a psychosocial intervention for harmful drinking by NSWs in primary care and solutions to overcome such barriers.

7.2 Methods

7.2.1 Settings and Sample

Two treatment development workshops were conducted with Indian mental health experts. One treatment development workshop each was conducted at

the T.T. Ranganathan Clinical Research Foundation (TTK Hospital), Chennai and the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore. The TTK Hospital is a pioneering voluntary organization dedicated to the treatment and rehabilitation of people with substance use disorders in a 65-bed treatment and rehabilitation centre. NIMHANS is a multidisciplinary institute at the frontline of patient care and academic excellence in the field of mental health and neurosciences in India. Participants for these workshops in India were identified in two ways as follows: a) the Director of TTK Hospital and the Professor at the Centre for Addiction Medicine at NIMHANS acted as key informants and invited eligible participants for the workshop; and b) the project team members invited eligible participants from their professional contacts residing in the two cities in which the workshops were conducted. The sampling strategy was a combination of convenience sampling and maximum variation sampling. The definitions, and pros and cons of these sampling strategies have been discussed in the previous chapter.

7.2.2 Study design

The treatment development workshops with the national experts comprised of Pile Sorting and Scheduling activities (Bernard, 2002). The pile sorting and scheduling activities were used to finalize the list of psychosocial strategies and to organize and schedule them into a coherent framework for the intervention. The participants were divided into smaller groups of randomly selected members. Each group was then provided with a set of index cards, with each card having one psychosocial intervention strategy from the list of strategies derived from the previous steps and a table with the definitions of these strategies (Table 7.1).

Table 7.1: Definitions of psychosocial strategies

<p>Psycho-education</p> <p>Providing information to help patients with AUD understand their symptoms, offer them hope and motivate them for treatment.</p>
<p>Personalised Feedback</p> <p>Measuring a person's alcohol consumption and its related behaviours and giving feedback about this to the person.</p>

<p>Motivational Interviewing</p> <p>Strengthening a person's own motivation for and commitment to change by exploring and resolving the contradictory emotions/beliefs about alcohol use.</p>
<p>Problem Solving</p> <p>Generating a list of problems, and evaluating and choosing options designed to address these problems, thereby reducing the helplessness and hopelessness associated with AUD.</p>
<p>Relapse Prevention</p> <p>Training to anticipate and cope with high-risk situations with the aim of preventing relapse of AUD.</p>
<p>Supportive Counselling</p> <p>Using a person's strengths and social supports to help them focus on coping with current issues.</p>
<p>Enlisting Social Supports</p> <p>Engaging important persons in one's social networks to encourage healthy behaviours and reduce alcohol use.</p>
<p>Social Skills Training</p> <p>Learning to use appropriate skills to handle social situations and manage related emotions, and to handle interpersonal relationships and functioning in the workplace, thereby reducing alcohol use</p>
<p>Vocational Counselling</p> <p>Helping a person with AUD to choose appropriate career options.</p>
<p>Cognitive Restructuring</p> <p>Learning to identify and question dysfunctional cognitions and cognitive processes with the aim of establishing more accurate or functional ones.</p>
<p>Geographical Cure</p> <p>Shifting the person with AUD temporarily to a new location or to a location where there is no or limited access to alcohol.</p>
<p>Relaxation</p> <p>Training of patients in methods of lowering their level of psycho- physiological arousal with the aim of reducing the physical and psychological features of anxiety associated with AUD.</p>
<p>Physical Exercise</p> <p>Encouraging bodily activity that enhances or maintains physical fitness and overall</p>

health and wellness.
Family Psycho-education Giving families information about AUD, helping them build social supports, and enhance problem solving, communication and coping skills.
Family Counselling Dealing with the family as a unit, addressing their unhelpful interaction patterns thereby resolving family conflicts associated with AUD.
Support Groups Facilitating the meeting of groups of persons who share a common experience of AUD, in order to provide support to each other and information and advice on health and related problems.

The groups were also presented with the data from the previous steps. Thus the groups had access to the information about global evidence of effectiveness, contextual evidence of effectiveness/impact, and explanatory models that has been described in Chapters 2-7. Each group was then asked to do the following: 1) 'sort' the strategies into meaningful piles and explain the reasons for doing so; and 2) 'schedule' the piled strategies into temporal phases of delivery with reasons for doing so. Participants were also allowed to add or remove strategies after providing a reason for doing so. They had to make their decisions based on the evidence presented to them and their own contextually relevant clinical experiences. Each group presented their temporal sequence diagram, and then a research team member guided a discussion comparing the frameworks with all participants.



Image 7.1: Participants at the Treatment Development Workshop at TTK ‘sorting’ and ‘scheduling’ psychosocial strategies into a coherent intervention.

Finally, focus group discussions (FGD) were conducted at each workshop, where participants were divided into two groups of randomly selected 6-9 members. Views regarding desired characteristics and competencies of lay counsellors, training and supervision requirements, and the likely risks and barriers in delivering the psychosocial intervention and ways to address them were elicited. I moderated the FGDs with other qualitative researchers; the FGDs were conducted in English, and audiotaped. A research team member took notes during this exercise and assisted the moderator in conducting the focus groups. A total of four FGDs, lasting for 60-90 minutes, were conducted in the two workshops.

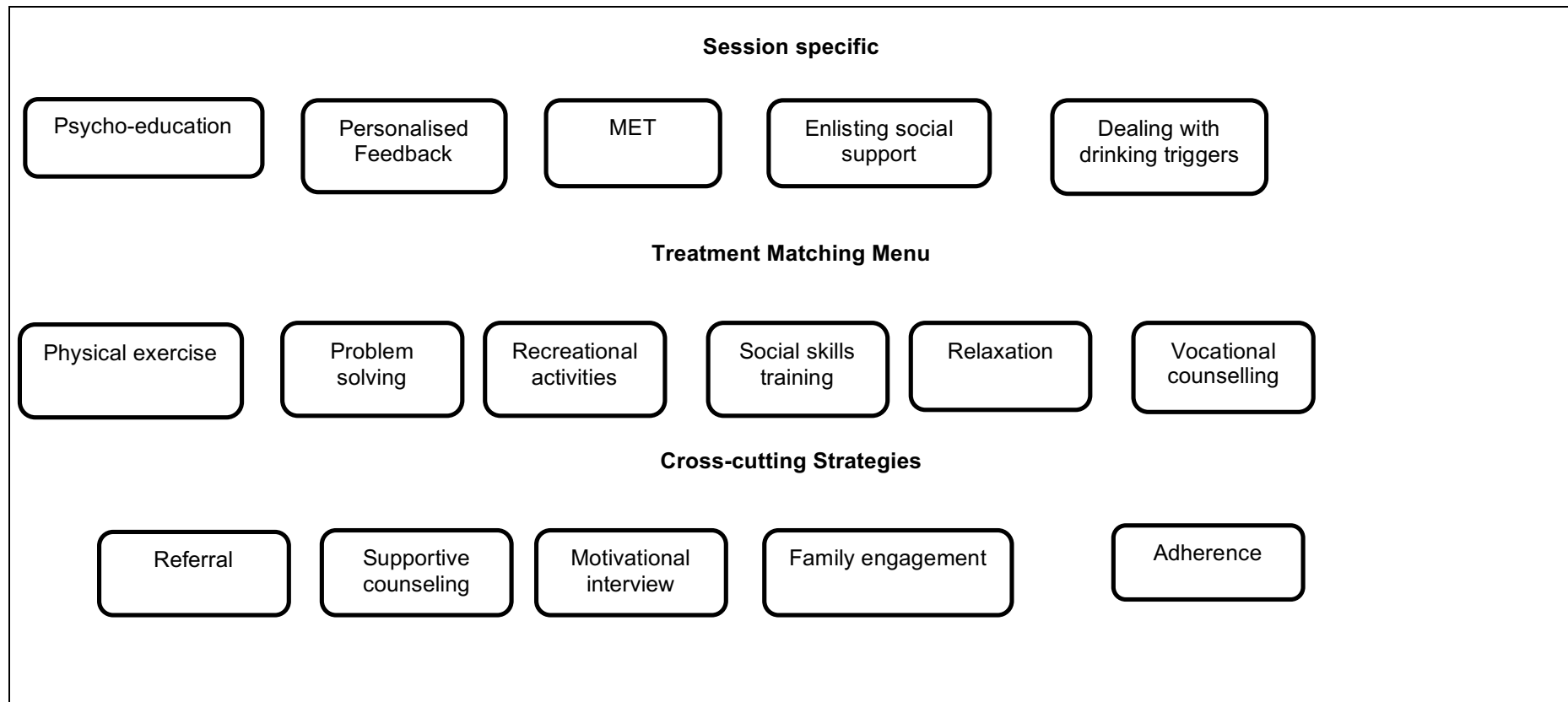


Image 7.2: Focus Group Discussion with participants at the Treatment Development Workshop at NIMHANS

7.2.3 Analysis

All the paper-based data, i.e. stacking of strategies into piles, diagrams/flow-charts of temporal sequence of psychosocial intervention delivery and narrative notes, were transformed into MS Word documents. An example of this is provided in Figure 7.2.

Figure 7.2: Pile sorting and scheduling of psychosocial strategies by one group of participants in the treatment development workshop



Thematic analysis was carried out to identify patterns of arranging piles and scheduling the psychosocial strategies, and to analyse the data from the FGDs (Braun and Clarke, 2006). Strategies that were added and removed by the workshop groups and the rationale for those decisions were compared for similarities and differences between the various groups. The figures of temporal sequence (e.g. Figure 7.2) were compared and contrasted using constant comparative method in an iterative fashion (Glasser, 1965); for example, the figure from pile scheduling activity of the first group was compared with that of the second; the results of this comparison with that of the third group and reverted comparing the third group with first and so on. Narratives of reasons for scheduling and comments made by participants during the FGDs supplemented this analysis.

The research themes from the question guide provided the overarching a priori deductive framework for the analysis. A preliminary coding framework was prepared for broad themes that guided the FGDs, for example socio-demographic characteristics of counsellor, competencies, etc. Subsequently, data from two FGDs was coded to refine the codebook. All FGD data were then coded with the revised codebook. Codes were then compared with each other for similarity in meaning. Similar codes were collapsed into inclusive categories and clusters of related codes were organised under other codes, forming hierarchies. Themes were derived by retrieving pieces of data pertaining to codes and by examining their meaning in relation to the research questions. Each theme was assigned a name and a descriptive phrase that best explained their meaning and united its individual codes on consistency. Finally, a list of themes was made and organised according to the research question they answered.

7.3 Results

30 mental health professionals (12 at TTK Hospital and 18 at NIMHANS) participated in the workshops: 13 psychiatrists (43.3%), 10 clinical psychologists (33.3%), and seven psychiatric social workers (23.3%). The sample comprised of 12 (40%) males and 18 females. 28 (93.3%) participants were working with a government or non-profit mental health teaching institute or/and hospital and two were in the private sector.

7.3.1 Added or modified strategies

The new strategies that were added by the various groups included 'family engagement', 'treatment adherence', 'dealing with drinking triggers', 'referral to specialists' (when appropriate), 'positive leisure activities', and 'healthy eating and sleeping routine'. Two groups recommended 'referral to specialists' as a strategy, while only one group each recommended the remaining strategies.

All groups felt that there was a thin line of distinction between strategies like 'family counselling', and 'family psycho-education'. Some participants expressed that 'family counselling' requires specialised skills such as identifying marital conflicts, addressing interpersonal and family-level conflicts and roles and patterns of communication, and that such skills would be beyond the abilities of NSHWs. Both the groups at the NIMHANS treatment development workshop suggested that 'family counselling', and 'family psycho-education' should be combined together as one new strategy called 'family engagement'.

Two groups felt that it is essential for NSHWs to understand when and to whom the patient should be referred for various reasons, and hence added 'referral to specialists' as a strategy to the list. 'Treatment adherence' was added as the group felt that it was important to ensure that the patient sticks to the prescribed treatment in order to avoid relapse. One of the groups felt that maintaining 'healthy eating and sleeping routine' helps in recovery from AUD and added it as a strategy.

7.3.2 Removed strategies

The groups removed the following strategies: cognitive re-structuring, vocational counselling, support groups, physical exercise and geographical cure.

Cognitive re-structuring was excluded as the groups felt that it required specialised skills (e.g. identifying cognitive schemas), which would be beyond the abilities of NSHWs. Vocational counselling was removed because it requires a lot of networking and awareness of the job market of the area. It was felt that this would be beyond the scope of the work that the NSHWs would be expected to do. Support groups were removed as there were concerns regarding privacy, confidentiality and feasibility in the context and setting in which the intervention was supposed to be delivered i.e. primary care. Geographical cure and physical

exercise were removed, as there was no systematic evidence for their effectiveness in treatment of AUD, and they had been primarily derived from the in depth interviews with patients, care givers, and mental health professionals.

7.3.3 Retained strategies

The following strategies were retained as they were: Motivational Interviewing (MI), psycho-education, personalised feedback, problem solving, relapse prevention, supportive counselling, enlisting social supports, relaxation, and social skills training.

Table 7.2 summarises the strategies that were modified, added, and excluded with the justification for those decisions.

The groups used distinctive ways to order the strategies into a temporal sequence. For example, one group proposed arranging the intervention into three phases: a) delivery of a 'core strategy' which binds together all the other strategies; b) other strategies to be used all through the course of intervention delivery; and c) strategies to be offered based on the patients' requirements in the follow-up sessions. Another group ordered the strategies based on the goals of the phases of intervention delivery: the goal of first phase would be to provide information and to link the information with the patients' problems e.g. personalised feedback; the goal of the second phase would be to help patients to solve problems related to their drinking e.g. social skills training; and the goal of the third phase would be relapse prevention.

7.3.4 Framework of the psychosocial intervention

The final scheduling of the strategies was based on the findings from the constant comparison analysis, and thematic analysis of the reasoning offered for pile scheduling. The first session comprised strategies like psycho-education and personalised feedback. The following two sessions, targeted at solving problems and enhancing coping, consisted of strategies like problem solving, social skills training etc. tailored to the needs of the client. The final session, comprising of strategies like relapse prevention, would empower the client with strategies to deal with the risk of relapse or recurrence of harmful drinking. Four strategies namely, MI, referral to specialists, supportive counselling and family engagement would be used as crosscutting strategies.

Table 7.2 Modified, new and excluded strategies with justification

Added/Modified strategies	Justification	Excluded strategies	Justification
Family engagement	The groups felt that there was a thin line of distinction between 'family counselling' and 'family psycho-education' and hence merged the two.		
Treatment adherence	To ensure that patient completes treatment and does not relapse.	Physical exercise	No systematic evidence.
Dealing with drinking triggers	To prevent relapse	Cognitive re-structuring	Requires specialised skills beyond the abilities of NSHWs.
Referral to specialists	To ensure that the counsellors know when and to whom to refer patients.	Vocational counselling	Networking and awareness of the job market required was felt to be beyond the scope of the NSHWs work.
Healthy eating and sleeping routine	To aid recovery.	Support groups	Concerns regarding privacy, confidentiality and feasibility.
Positive leisure activities	To distract from urges to drink.	Geographical cure	No systematic evidence

7.3.5 Delivery of the intervention

The findings from the FGDs are organized under the following themes: characteristics of the counsellor; counsellor competencies required; training and supervision; and potential barriers, risks and harms in delivering psychosocial interventions and ways to address them.

a) Characteristics of the NSHW

- i. Existing soft skills: Most participants agreed that the NSHW should have the following basic characteristics before getting trained: *'open-mindedness'*, *'non-biased and non-judgmental attitude'*, *'flexibility in thinking'*, *'interest in and commitment towards community work'*, and *'understanding of the community'*. Some participants said that the NSHW should be a *'people's person'*, should be *'embedded in the community'* and enjoy some *'standing/influence within the community'*. All participants felt that the person should have the basic skills of *'listening'* and *'communication'*, and the *'knowledge of and experience in handling crisis situations'*. Overall, there was an agreement that existing soft skills are important to start off with and further skills could be built up through training and supervision.
- ii. Gender: There was considerably less agreement over the gender of the NSHWs. A few participants believed that female NSHWs would be preferred and accepted by the community, others opposed this view. Participants who believed that female NSHWs would be accepted by the community argued that women are more empathetic and given respect in the community. On the other hand, other participants reasoned that the nature of disorder, the target population for the intervention being male, and concerns about the safety and mobility of female counsellors in the community especially during late hours, made it more feasible and acceptable to have male NSHWs. Finally a few participants felt that both male and female NSHWs should be recruited. Thus there was no consensus within or across groups with regard to the gender of the counsellor.

- iii. Educational qualifications: There was no consensus on the educational qualifications of the NSHW either. Some participants felt that delivering strategies like MI would require at least a graduate degree in psychology or social work. On the other hand, other participants felt that education was not an important consideration and illiterate persons or persons with lower education levels should also be considered. They said that if the psychosocial intervention strategies were broken into simpler and smaller steps, they could be effectively delivered by less educated persons. Ultimately, most participants agreed that as the work profile would include at least some basic documentation, the NSHW should at least have completed secondary school education.
- iv. Work experience: With regard to previous work experience, most participants reported that a person who has had some job/voluntary work experience in a health project or community work should be preferred. Generally, some experience of working in the community health sector was thought of as an advantage in the NSHWs who would be recruited.
- v. Caste considerations: A few participants also voiced their opinion regarding the caste of the NSHW; since caste dynamics play a dominant role, especially in rural India, patients might not want to seek treatment from a lower caste NSHW and might prefer a NSHW from their own caste. However, participants also recognized that it would be beyond the scope of a health programme to match the caste of patient and the NSHW. There was no consensus on whether matching on caste of NSHW and patient should be done.
- vi. Community background: Some participants felt that the NSHW should be from the same community, as he/she would know the people and dynamics of that particular community better than a NSHW from outside the community. However, other participants disagreed as they foresaw problems with confidentiality and trust i.e. patients may not be willing to share their personal issues or problems with a NSHW who is from the same community and whom they might know socially. There was no consensus on whether the NSHWs should or should not be from the community in which they would eventually deliver the intervention.

A few participants felt that there should not be any criteria for selection of NSHWs and anyone who is available, suitable and motivated should be recruited. Also, some participants suggested that rather than having a homogeneous group of NSHWs selected on the basis of pre-specified criteria, the project should recruit NSHWs with diverse characteristics including gender, education and occupational background. Finally, some participants felt that recovering persons or persons who have had history of alcohol problems in the family should also be considered as they might have higher level of motivation to perform well in such a job.

b) Counsellor competencies

- i. Counselling skills: There was widespread agreement regarding the competencies that a counsellor should acquire to enable him/her to effectively deliver the psychosocial intervention. These skills could be segregated into 'general skills', 'counselling specific skills' and 'project specific skills'.

Some 'general skills' that were commonly reported included knowledge of local rituals and culture, ability to learn, ability to be flexible, ability to think quickly, ability to connect, networking skills, clarity of communication, ability to keep one's beliefs and prejudices out of the counselling practice, and ability to assimilate information and integrate it effectively. 'Counselling specific skills' included skills like listening, paraphrasing, reflection, questioning skills, 'Rogerian' skills, and ability to motivate patients. The 'project specific skills' included record keeping and documentation skills, and organisational skills.

Some other competencies which were listed by fewer participants include: ability to adapt knowledge to individual patient's situation, ability to set priorities, ability to not get side-tracked by family members of patients, ability to engage with families of patients without blaming them, and an ability to understand one's own limitations as a counsellor i.e. what can and cannot be done as a counsellor.

- ii. Existing skills: All the participants agreed that most of the skills required to deliver a psychosocial intervention can be taught or developed but

passion and commitment for the work cannot be taught. Hence, it was felt that it was important to assess the motivation and interest of the person during recruitment, training and on-going supervision. A few participants, however, argued that generally perceived soft skills/competencies are '*core competencies*' and most of these competencies can be imparted through extensive and rigorous training and supervision even if they are not pre-existing in the NSHWs.

- iii. Competency assessment: Some participants opined that certain competencies could be assessed during recruitment through techniques like structured interview, problem solving exercises, and group discussion. These techniques were believed to be useful in assessing '*soft skills*' such as listening and communication skills.
- iv. Training and supervision: There was general agreement in the groups that the NSHWs should receive rigorous training in the beginning and booster training sessions at regular intervals. The groups also recommended that the training should be conducted by experts working in the field of substance abuse disorders, such as psychologists, psychiatric social workers, and psychiatrists. Participants suggested that structured training modules should be developed and should include modules on awareness building in the community, mobilizing the community, and soft skills required in counselling.

All the participants underlined the need of supervision of the NSHWs by mental health experts. In addition, participants suggested that supervision should be an on-going process wherein initially it could be provided more frequently and the frequency could be reduced as the NSHWs became more experienced. Various methods of supervision were suggested including audio recording of the sessions, shadowing of the NSHWs by the supervisor as the former delivered counselling to patients, and role-plays. Few participants also suggested that there were tools available online which could be used to measure competency of working in the AUD field. Some participants also pointed out that supervision should provide emotional and psychosocial support to the counsellors themselves.

c) Barriers to delivering the psychosocial intervention

The barriers that the NSHWs could potentially face are classified into practical, psychological, and socio-cultural barriers using the framework from the engagement session treatment manual by Zuckoff et al (2004).

- i. Practical barriers: Some barriers that were discussed included the out of hours unavailability of the NSHWs, loss of daily wages for patients unable to go to work as they were attending counselling sessions, and lack of transportation for patients to reach the primary healthcare centre (PHC). Few participants felt that the number of sessions of the intervention would determine adherence and if the number of sessions were more than two, the adherence rate would drop drastically for subsequent sessions. Also, the groups had concerns about female NSHWs having to visit communities to see patients in late evenings.
- ii. Psychological barriers: The most common psychological barrier reported was one related to the nature of the illness i.e. the patient might not perceive his drinking habit as harmful and the intervention may be perceived by the patient as an '*interference in personal life*'. In addition, some patients might feel that the NSHW is not competent enough to handle his issues and does not have any power to prescribe a tangible treatment, e.g. injections or medicine, and hence would want to be seen only by a doctor. A potential solution suggested to this barrier was to integrate the NSHW into established practice in the PHC so that he/she is seen as a part of the healthcare ecosystem and not an add-on. Another related barrier was unwillingness to continue psychosocial intervention as instant results of treatment are not forthcoming, something which is generally expected from medical treatments.
- iii. Socio-cultural barriers: Obstacles related to the social-cultural milieu were discussed in great detail in all the FGDs. One of the major obstacles would be stigma associated with being diagnosed with and seeking treatment for what is perceived as a mental illness. Some participants also felt that if the programme was specifically positioned as one targeting AUD, people would not participate in it. A potential strategy suggested to deal with this obstacle was to generate awareness about

the programme in the community. A related barrier was that since the NSHW would be exclusively offering treatment for AUD then he/she would himself/herself get stigmatised within the healthcare setting and patients would not prefer to seek treat from such a person. A potential solution suggested was to give the NSHW other responsibilities in the primary healthcare setting to avoid stigmatisation. This would also serve the purpose of overcoming the organisational barrier about acceptance of NSHW by the other primary healthcare staff. Some other concerns discussed by the participants included heavy case load at the primary health centre (PHC) restricting the opportunity for offering the psychosocial intervention; and lack of adequate space at the PHC compromising privacy required for delivery of the psychosocial intervention. A few participants were concerned about the possible opposition and threats to the NSHW from the '*liquor lobby*' in the community and suggested the development of a support system for NSHW.

d) Potential risks and harms in a NSHW delivering the intervention

Most participants agreed that if the NSHW failed to identify co-morbid disorders or severity of the problem and consequently did not refer the patient to an expert at the right time, then it could pose a risk to the patient. An example of such a situation, which was cited in all the FGDs, was suicidality in a patient going unidentified by the NSHW. Similarly, all the participants agreed that the NSHW could pose harm to the patient if she/he is unable to detect alcohol dependence and gave advice to the patient to completely stop drinking without medical supervision. One of the potential strategies suggested to avoid this risk was to provide a guideline to the counsellor that clearly describes when and whom to refer the patient to. Other strategies included providing a clear list of DOs and DONTs to the counsellors, and extensive training on co-morbid conditions.

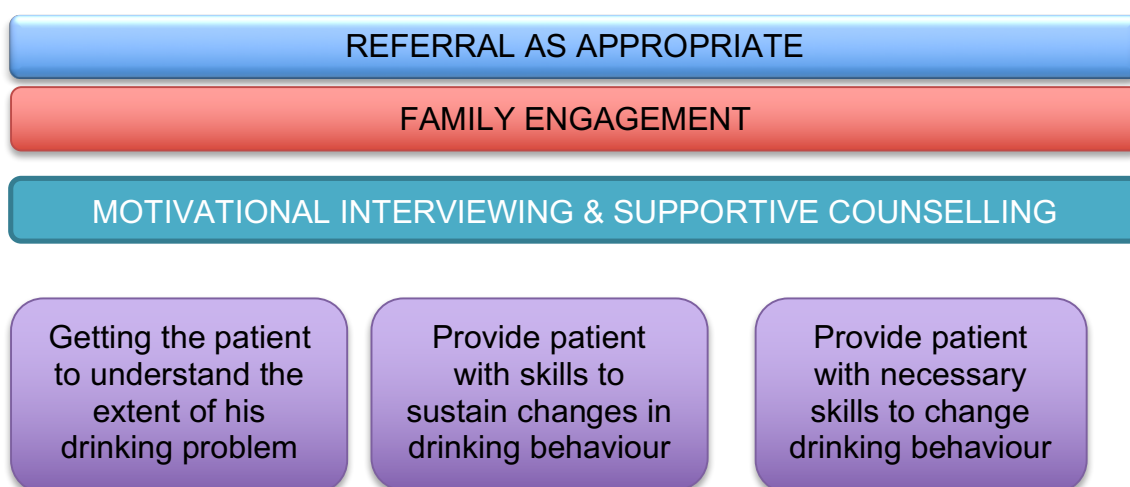
Other related risks included not delivering the psychosocial intervention as described in the manual, and not respecting the boundaries and responsibilities of a NSHW. A potential strategy suggested to overcome this barrier was close supervision during the early phase of the programme. Some participants

believed that there was a risk of the NSHW becoming '*powerful and mighty*' in the community and taking moral positions on alcohol drinking. Some participants were also concerned about the safety of the NSHW i.e. if something happened to the patient because of his/her drinking, relatives or significant others of the patient could pose a threat to the NSHW.

7.4 Output

In this step of the intervention development process the aim was to use the outcomes of all the previous steps to generate a theoretical framework for the delivery of the psychosocial intervention for harmful drinking, which was now named as Counselling for Alcohol Problems (CAP). At the end of this process there remained a list of strategies that were perceived to be mutually complementary and could be arranged into a coherent intervention to be delivered over four sessions. The emerging structure of the CAP at the end of the treatment development workshop was as follows (Figure 7.3): The core of the intervention would be MI and supportive counselling. The family members would be engaged through the course of the intervention and referrals to appropriate professionals/agencies would be made as and when required. The initial sessions would be focused on getting the patient to understand the extent of his drinking problem and the subsequent sessions would aim to provide him with the necessary skills required to change his drinking behaviour. The intervention would then end with providing the patient with the skills required to sustain any changes that he might have made to his drinking behaviour.

Figure 7.3: Framework of the emerging CAP intervention.



As in the previous step, there would be concerns about the methodology followed i.e. a relatively small number of people deciding whether certain psychosocial strategies should be retained or excluded from the developing intervention. However, as mentioned in the previous chapter the intervention development process has inbuilt checks and balances that do not allow a single step to determine the content of the intervention. For example, in the treatment development workshops 'cognitive restructuring' was felt to be too sophisticated to be delivered by lay counsellors and hence was excluded. However, based on the experience of the case series (Chapter 8) a very limited component of 'cognitive restructuring' was introduced into the developing intervention.

Finally, the treatment development workshops also helped to brainstorm issues like skills that would be required by the NSHWs, training and supervision and barriers that the NSHWs would face while delivering the psychosocial intervention. These were expected to inform the process of recruitment, training, competency evaluation, and implementation of the CAP intervention in the community.

On the one hand, quite a lot of the lessons learnt from the FGDs informed the subsequent steps of the intervention development process. On the other hand, a lot of other suggestions made in FGDs could not be implemented for a range of reasons. The following section describes how some of the suggestions were implemented and why others could not be implemented. As suggested in the FGDs, an assessment of existing soft skills in the potential NSHWs was rigorously done in the initial recruitment procedure as well as in the subsequent training. Furthermore, during the intervention delivery phase of the intervention development process a close eye was kept on these soft skills (e.g. listening skills) during supervision. However there were certain other criteria over which we had limited control e.g. gender, qualifications, work experience of the applicants, and source community. However we do not think these were major considerations with a clear answer, as we did not manage to get any consensus in the FGDs on most of these criteria. Furthermore, as we had one eye on the eventual scalability of the intervention being developed, we thought it prudent that there shouldn't be too many restrictions on eligibility criteria lest it become difficult to recruit NSHWs in a resource poor setting. Finally, it was decided not to implement the suggestion about caste matching as the issue of caste is not a

major one in Goa and it was also agreed in the PREMIUM team that it was inappropriate for a secular healthcare programme to be implementing something which could be seen as propagating a social ill.

As suggested in the FGDs a rigorous process was followed to select, train, and supervise the NSHWs to ensure people with the appropriate existing soft skills were selected, and their competencies were built up and sustained through rigorous training and supervision. The skills that the NSHWs were trained in included the right mix of generic counselling skills (e.g. listening skills) and intervention specific skills (e.g. rolling with resistance). Other suggestions that were implemented included delivery of training by experts, structured competency assessment methods, and use of audio taped sessions as well as direct observation of intervention delivery as a part of supervision.

Some other suggestions that were not implemented were as follows. We did not do any awareness building in the community or community mobilisation as the intervention was designed to be delivered in the PHC and the integration of the programme into the routine working of the PHC was given precedence. Although it was suggested that supervision of the NSHWs should be done by experts we tested a model of peer supervision (details in Chapter 9) as an expert led supervision model would not be sustainable in a scaled up programme in low resource settings because of shortage of mental health specialists.

During the course of the case series and pilot RCT, described in subsequent chapters, we came across some of the barriers to successful delivery of the intervention that were predicted in the FGDs. These included barriers like loss of daily wages for patients unable to go to work as they were attending counselling sessions, and lack of transportation for patients to reach the PHC, adherence rates dropping after first two sessions, patient not perceiving his drinking habits as harmful, lack of confidence in a psychosocial intervention, expectation of medications etc. Being aware of such barriers in advance allowed us to prepare contingency plans and to develop rapid responses to overcome the barriers. Further details about such barriers and how they were overcome are described in detail in subsequent chapters of my thesis.

To summarise, at the end of this step of the intervention development process we had the framework for CAP, an intervention for harmful drinking, which was informed by both global and contextual evidence and made up of components which were potentially acceptable to NSHWs and patients, and feasible and safe to be delivered by NSHWs in primary care. The subsequent steps describe how this framework was used to develop a manual for CAP and how it was iteratively adapted based on mixed methods participatory research findings to generate the final version to be tested in a definitive RCT.

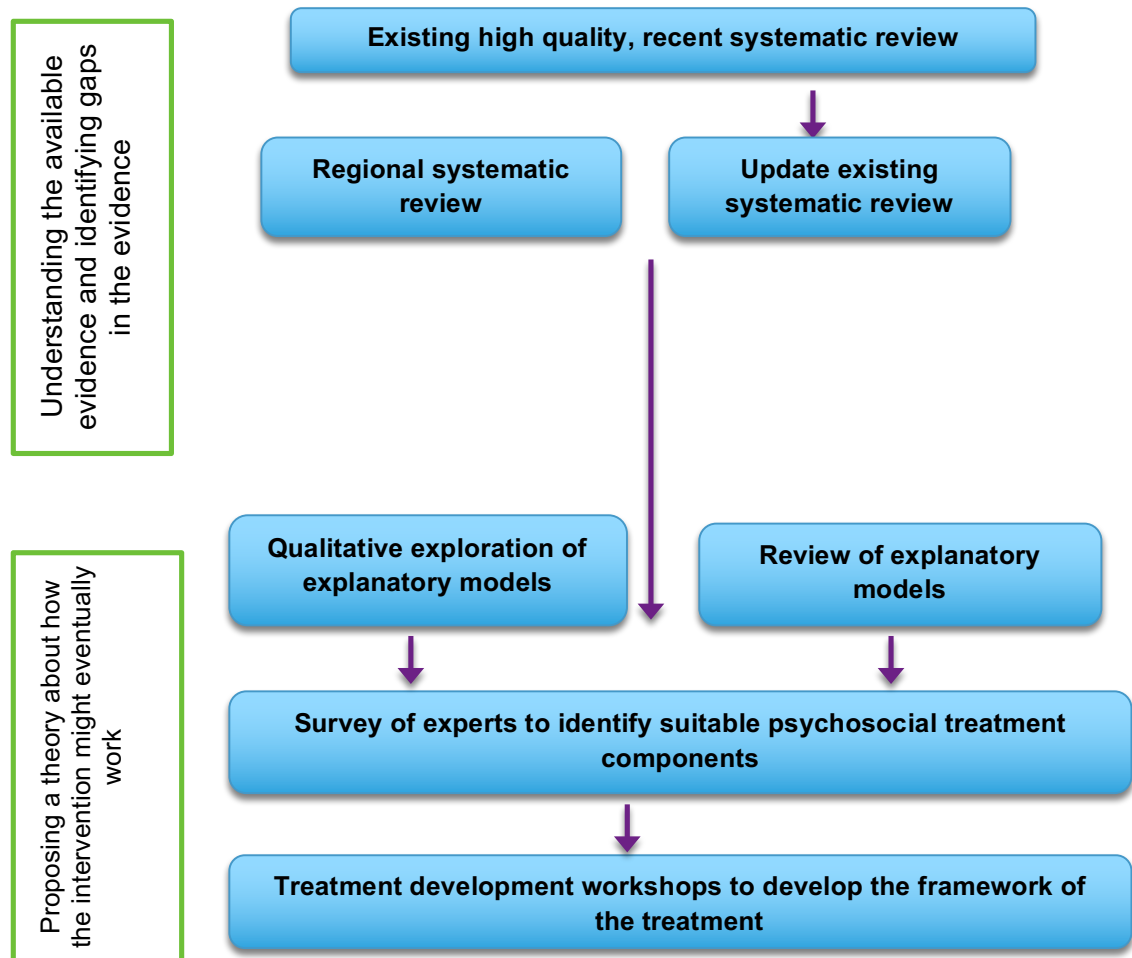
Chapter 8: Clinical Case Series: Experiences of delivering MI in India^{§§}

8.1 Background

The sequential steps of the intervention development process described in the previous chapters first yielded a list of effective and acceptable evidence based psychosocial intervention strategies that were perceived to be feasible and safe to be delivered by non-specialist health workers (NSHW) and subsequently organised into a coherent theoretical framework to form the Counselling for Alcohol Problems (CAP) psychosocial intervention (Figure 8.1). Finally during the treatment development workshops described in Chapter 7, Motivational Interviewing (MI) was unanimously selected as the 'core' strategy for the CAP intervention. Although the previous steps identified a range of psychosocial intervention strategies they could not obviously be delivered as a set of discrete components. What was needed was a psychosocial intervention strategy that could hold all the components together so that they could be delivered based on patients' needs. Among all the evidence based psychosocial strategies identified only MI had the potential to do that as it is a counselling 'style' which can be used to deliver a range of psychosocial component strategies. It is important to note that CAP is not 'just MI' but a set of contextually appropriate psychosocial intervention strategies delivered in a MI consistent style. Thus MI was conceptualized as the 'scaffolding' around which the other identified strategies would be delivered.

^{§§} Author contribution to the methods: I contributed to the content analyses of the various potential treatment manuals, contributed to the development of data collection tools, delivered MI to patients, participated in supervision, co-authored the CAP manual, contributed to the revision of the manual based on incoming data, analysed the data, synthesised the results, and interpreted the findings.

Figure 8.1: Progress of the intervention development process



The group of international experts involved in the PREMIUM project then identified various relevant intervention manuals that could potentially help guide the development of the CAP manual. The manuals that were short-listed were a) Motivational Enhancement Therapy (MET) manual from Project MATCH (Matching Alcohol Treatments to Client Heterogeneity) (Miller et al., 1999), b) Cognitive Behaviour Coping Skills Therapy (CBCST) manual from Project MATCH (Kadden et al., 2003), c) COMBINE (Combined Pharmacotherapies and Behavioural Interventions for Alcohol Dependence) manual (Arciniega et al. 2002), and d) Helping Patients Who Drink Too Much: A Clinician's Guide (NIAAA, 2005). A content analysis of these manuals was then carried out by evaluating them on various criteria (Appendix 5), emphasizing the adequacy of the coverage of identified psychosocial intervention strategies and its suitability for delivery by NSHW. More specifically this included the following:

- Suitability for delivery by a NSHW,

- Extent to which therapist engagement issues were tackled,
- Description of number, duration and structure of sessions,
- Description of psychosocial intervention techniques used,
- Appropriateness of the language for use by NSHWs in the relevant cultural context,
- Availability of supporting material (e.g. patient information material),
- Flexibility in delivery to adapt to patient characteristics (e.g. less literate patients), and,
- Extent to which barriers to delivery and solutions to them were addressed.

Based on this process, the MET manual from Project MATCH was selected as a guiding manual for the next step of the intervention development process as it came closest to having most of the characteristics described above.

This chapter describes the experiences of implementing the Project MATCH MET treatment, with the goal of examining the competencies needed to deliver the core (viz MI) of the emerging intervention and its acceptability and feasibility of delivery. The specific objectives of this step of the intervention development process were:

- a) To describe the processes in and challenges to acquiring competencies in delivering MI for a clinical team comprising mental health practitioners with the goal of building a team of experts who could subsequently train and supervise the lay counsellors who would eventually deliver the CAP; and
- b) To describe the experience of the delivery of MI, by specialists, as defined in the MATCH manual, and use this experience to draft and refine CAP by:
 - i. Documenting the challenges and facilitators to delivery of MI;
 - ii. Elaborating the techniques used in delivering MI;
 - iii. Defining how the additional strategies, identified in the previous steps, can be added to the MI 'scaffolding'; and

- iv. Identifying any additional strategies or techniques that needed to be incorporated into the new intervention.
- c) To use the experiences and data from (a) and (b) above to write the first draft of the CAP manual.

8.2 Methods

8.2.1 Study design

Treatment cohort with before and after design. The intervention was delivered to a group of eligible and consenting patients recruited from various sources and a range of data needed to meet the study objectives were collected before, during and after completion of intervention.

8.2.2 Setting

The study was implemented in Goa and Satara in India, both settings described in Chapter 5. In Goa, participants were recruited in Primary Health Centres (PHC), private General Practitioners' (GP) surgeries and directly from the community. In Satara, participants were recruited in PHCs, and a de-addiction centre. The publicly funded PHC is the first port of call in India for people who wish to seek health care in the public system. The de-addiction centres in India generally provide drug treatments (e.g. medically assisted detoxification, anti craving medications) for alcohol dependence and do not provide any structured evidence based psychosocial interventions for Alcohol Use Disorders (AUD).

8.2.3 Sample

A convenience sampling strategy was used to select participants for this case series. Convenience sampling is a non-probability sampling technique in which participants are selected because of their convenient accessibility. Compared to probability sampling, convenience sampling is easier to implement, cheaper, requires lesser time, and allows gathering of useful data without a need for a sampling frame that might sometimes be difficult to access. However, since the sampling frame is not known, and the sample is not chosen at random, it means that the sample is less likely to be representative of the population being studied.

Eligible participants with AUD were identified through a range of strategies as follows:

- a. Direct referrals by doctors from PHCs and private GP clinics;
- b. Screening in the waiting rooms of private GP clinics and PHCs;
- c. Direct referrals from psychiatrists;
- d. Direct referrals from other medical specialists (e.g. Cardiologists, Internal Medicine Consultants etc.);
- e. Screening at and referrals by a de-addiction centre in Satara;
- f. Self-referred clients; and
- g. Screening after a community awareness programme in a slum area in North Goa.

8.2.4 Inclusion criteria

There are several screening tools that can be used to identify probable AUD in adults in a range of settings. Table 8.1 describes some of the more commonly used screening tools for AUD.

Table 8.1: Screening tools used to detect probable AUD

Screening tool	Substance type		Administered by	
	Alcohol	Drugs	Self	Clinician/Researcher
Alcohol Use Disorders Identification Test (AUDIT)	✓		✓	✓
AUDIT-C	✓		✓	✓
CAGE	✓			✓
CAGE-AID	✓	✓		✓
Michigan Alcohol Screening Test (MAST)	✓		✓	✓
Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)	✓	✓		✓

The CAGE questionnaire is used extensively in primary care settings because it is short (four questions), simple, and easy to remember (Ewing, 1984). The CAGE-AID (Adapted to Include Drugs) (four questions) is a version of the CAGE questionnaire which has been adapted to include drug use in addition to alcohol use (Brown, 1995). Tests, such as the Michigan Alcoholism Screening Test (MAST) (25 questions) (Selzer, 1971) or the Alcohol Use Disorders Identification Test (AUDIT) (10 questions) (Saunders et al, 1993), are relatively longer but allow the collection of more detailed information about patterns of alcohol consumption. The AUDIT-C (3 questions), a shorter version of the AUDIT, focuses only on the quantity and frequency of drinking and not its impact, unlike the AUDIT (Bush et al, 1998). The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) (eight questions) screens for risky use and covers tobacco, alcohol, cannabis, cocaine, amphetamine-type stimulants (including ecstasy) inhalants, sedatives, hallucinogens, and opioids (WHO Group, 2002). For the purpose of PREMIUM, the requirement was an validated (preferably locally) tool that could identify people with probable 'harmful drinking'. AUDIT came closest to those requirements as it was able to differentiate 'harmful drinkers' from 'hazardous' and 'dependent drinkers', had been validated in India and extensively used in Goa (details below).

Adult (18 years and above) men who scored more than 12 on the Alcohol Use Disorders Identification Test (AUDIT), or who had a clinical diagnosis of AUD from a mental health professional were included into the study after informed consent. The AUDIT is a 10-item screening questionnaire developed by the World Health Organization (WHO) for the detection of AUD (Saunders et al., 1993) (Appendix 6). It has been validated in India (Pal et al., 2004), and used in cross-national studies, including India (Babu, 1997). For a previous study, the AUDIT has been translated into Konkani (Goan vernacular), using a systematic translation-back translation method with two teams of translators, followed by an item-by item analysis and selection by consensus (Silva et al., 2003). The Marathi (vernacular from Satara) version of the AUDIT was used in Satara but this version had not been used in any previous studies.

Although the WHO recommends a cut off score of 15 on the AUDIT for harmful drinking it allows for varying the cut-off score depending on the country's drinking patterns, the alcohol content of standard drinks, and the nature of the screening program (Babor et al., 2001). There is ample evidence from research around the world to indicate that cultural differences significantly influence the cut-off points on the AUDIT. In a study from Nepal, India's neighbour, the best cut off value for harmful drinking on the AUDIT was ≥ 9 (Pradhan et al., 2012). The cut off scores have varied by countries with cut-off scores for dependence in Switzerland ranging from 10 to 13 (Daeppen et al., 2000), ≥ 11 for alcohol dependence among hospitalized Chinese patients (Tsai et al., 2005), 10 and 13 as cut offs for harmful drinking and alcohol dependence, respectively in a Tibetan population (Guo et al., 2008), and ≥ 13 for alcohol dependence in a French speaking population (Gache et al., 2005). The addictions experts in the investigators group in PREMIUM highlighted these variations in cut off scores and stressed that the WHO recommended cut off score would not help to identify all harmful drinkers in an Indian population. Hence, for the purpose of PREMIUM the lower end of the cut-off score for harmful drinking was reduced to 12.

8.2.5 Exclusion criteria

Men with harmful drinking co-morbid with severe mental disorder or co-morbid with serious physical illness, that could prevent engagement with counselling, were excluded.

8.2.6 Therapists

Four specialists and one experienced NSHW delivered the intervention. Their details are as follows:

a) Specialists: These included i) a psychiatrist with nine years of experience of working in the mental health field in India with specific focus in addiction medicine, ii) the author of this thesis, a psychiatrist with 10 years of experience of working in the mental health field, including addiction units, in Goa and the UK, and iii) two psychiatric social workers with a Masters in Social Work (MSW)

and 12 years and 4 years experience respectively of working in the field of addictions and mental health.

b) Non-specialist: The NSHW had a postgraduate diploma in computer applications (PGDCA) with three years of experience counselling people with mental disorders. She had experience of working as a lay counsellor in the MANAS trial, one of the largest trials of psychosocial interventions in the developing world (Patel et al., 2010) and for PREMIUM she was promoted to the role of Counsellor Supervisor.

8.2.7 Training

All five therapists completed MI training before starting to deliver it in the case series. Four of the therapists attended a five-day MI training workshop conducted in India by Jeff Allison (a social worker with extensive experience in MI training since 1996) and Guy Undrill (a consultant Psychiatrist and a member of the Motivational Interviewing Network of Trainers). One therapist attended a two-day MI training workshop in Birmingham, UK led by Pip Mason, a MI trainer with experience of MI training since 1998.

8.2.8 Intervention

MI was delivered as per the Project MATCH MET manual (Miller et al., 1999). The intervention was to be delivered primarily in face-to-face sessions, but the therapists were given the option of delivering it over the phone if a patient was unable to attend the clinic for some reason. The delivery of MET in the Project MATCH manual is divided into three broad phases namely: 'Building motivation for change' (Phase 1), 'Strengthening commitment to change' (Phase 2) and 'Follow-through strategies' (Phase 3). The psychosocial techniques used in the three phases are listed in Table 8.2.

Table 8.2: Psychosocial intervention techniques used in Project MATCH MET

Phase	Psychosocial Techniques
Phase 1	<ul style="list-style-type: none">• Eliciting self-motivational statements,• Listening with empathy using reflection,

Phase	Psychosocial Techniques
	<ul style="list-style-type: none"> • Questioning, • Presenting personalised feedback, • Affirming the client through enhancing self responsibility, • Handling resistance, • Reframing, and • Summarizing.
Phase 2	<ul style="list-style-type: none"> • Recognizing commitment to change, • Discussing a plan for change, • Communicating free choice, • Consequences of action/inaction, • Giving of information/advice, • Emphasizing abstinence, • Dealing with resistance, • Recapitulating and asking for commitment
Phase 3	<ul style="list-style-type: none"> • Reviewing progress, • Renewing motivation, and • Redoing commitment

Some of the key psychosocial techniques used in the sessions are described in detail in Table 8.3.

Table 8.3: Some Psychosocial intervention techniques described in Project MATCH MET manual

TECHNIQUE	DESCRIPTION
Elicit self motivational statements/Change talk	<p>Acknowledge 'change talk' of the patients, the therapist and evoke 'change talk' from the patient using various strategies as follows:</p> <ul style="list-style-type: none"> • Evocative open-ended questions (e.g. "In what ways does your drinking concern you?") • Looking ahead (e.g. "What might your life look like in five years if very little changes?")
Express empathy	Convey great respect for the patient and promote freedom of choice and self-direction.
Develop discrepancy	Enhance and focus the patients' attention on the discrepancy between where they are and where they want to be with regard to drinking behaviour.
Roll with resistance	Not meet patient's resistance to change head-on but rather 'roll with' the momentum, with the goal of shifting patient's perceptions in the process.
Support self efficacy	Persuade patient that it is possible to change their own drinking and thereby reduce related problems.
Reflective listening	Listen carefully to what the patient is saying, then reflect it back to the patient, often in a slightly modified or reframed form.
Affirmation	Seek opportunities to affirm, compliment and reinforce sincerely the patient and his motivation to

TECHNIQUE	DESCRIPTION
	change.
Reframing	Invite the patient to examine his perception about his drinking and its impact in a new light or a reorganized form.
Summarising	Summarise to review the direction of the session or to change direction of the session, to slow down the pace of the session and to clarify what has been discussed so far in the session.

The three phases of Project MATCH MET encompass four treatment sessions delivered at week 0, week 1-2, week 6, and week 12. The first two sessions focus on structured feedback from the initial assessment, future plans about drinking behaviour, and motivation for change. The final two sessions provide opportunities for the therapist to reinforce progress made by the patient, encourage reassessment of the situation by the patient, and provide an objective perspective on the process of change.

The Project MATCH MET manual emphasises that, wherever possible, the patient should be strongly urged to bring a significant other (SO) (spouse, family member, friend) to the first two sessions. During these sessions, the SO is actively involved in the treatment process and emphasis is placed on the patient and SO working collaboratively on the drinking problem. This process involves raising awareness about the extent and severity of the alcohol problem, strengthening the SO's commitment to help the patient overcome the drinking problem, elicit feedback from the SO that might help the client overcome the drinking problem etc.

Thus, the Project MET manual emphasised the two strategies identified as core strategies in the treatment development workshops, namely MI and family engagement. Any strategies/techniques that needed to be used in the case series, over and above those described in the Project MATCH MET manual, would be derived from the strategy list that was developed after the formative stages described in the preceding chapters. These additional strategies/techniques could be delivered at any stage of the intervention as per the needs of the patient.

8.2.9 Supervision

Richard Velleman (RV), an Emeritus Professor of Mental Health Research, UK supervised the therapists. Prof Velleman is a clinical psychologist who has worked as a clinician and researcher in the addictions and mental health fields for more than 30 years. He has been running services based on the MI model for the past 20 years and the MI model forms the basis for his book, *Counselling for Alcohol Problems* (Velleman, 2011)

There were two types of supervision sessions, namely a) expert led supervision, and b) peer group supervision.

a) Expert led supervision: RV led these weekly supervision sessions. The translated transcripts of sessions to be discussed were circulated to all group members in advance of the supervision session. Each therapist and RV then rated the transcript using the Motivational Interviewing Target Scheme (MITS 2.0) (<http://www.motivationalinterviewing.org/motivational-interviewing-target-scheme-mits-20>). MITS is an instrument developed by MiCampus to measure MI consistent practice. The instrument measures 10 therapist behaviours that amount to a comprehensive description of observable practice of MI. These 10 target behaviours are: activity emphasis, posture, empathy, collaboration, evocation, independence, navigation, contrasts, structured brief tactics and information/advice. The details of these target behaviours are described in Table 8.4.

On the MITS, each of the first seven target behaviours have to be compulsorily scored on a scale of 0 to 4 and the remaining three are optional and scored on a scale of 1 to 4. These scores are given based on whether the evidence of practice (on the tape or transcript) does not (0), partly (1), moderately (2), substantially (3) or completely (4) supports the target definition. A total and mean score is then generated which in turn can be transformed into a 'standard' (4,3,2,1,1^{alpha}) which represent no significant, partial, moderate, substantial and very high degree of MI consistent practice respectively.

Table 8.4: Target behaviours assessed in MITS 2.0 (Directly extracted from the MITS manual)
(<http://www.motivationalinterviewing.org/motivational-interviewing-target-scheme-mits-20>)

Target Behaviour	Description
Activity Emphasis	The practitioner gives emphasis to an activity fitting to the prevailing task and demonstrates a capacity to change activity, when appropriate, to maintain helpfulness.
Posture	The practitioner gives evidence of being compassionate, courteous, respectful, considerate, serious, caring and friendly. The practitioner acts as a benevolent witness to change.
Empathy	The practitioner attempts to demonstrate accurate understanding of the persons thoughts and feelings through the use of reflective statements. The practitioner appears to be genuinely curious about the person and what s/he has to say.
Collaboration	The practitioner fosters a collaborative ambience in the conversation and encourages the person to articulate her/his ideas so that these are placed at the centre of the conversation. Any decisions are reached with a sense of purposeful partnership.
Independence	The practitioner is encouraging, supportive and accepting of the person's independence. The practitioner seeks to enhance the person's sense of control and freedom of choice.
Evocation	The practitioner encourages the person to articulate her/his own motivations for change, rather than attempting to inform, advise or direct the person. When the person articulates her/his own motivations for change and

Target Behaviour	Description
	ideas about how change might happen, the practitioner accepts these.
Navigation	The practitioner navigates the conversation so that discussion of the behaviour change target and/or focal problem is maintained largely at the centre, and does so without causing a discordant ambience or resistant behaviour from the person.
Contrasts	The practitioner attempts to evoke, highlight and explore the ways in which the focal problem is inconsistent with the person's goals, aspirations, beliefs or values. This is done in such a way that the person's sense of self-worth is maintained or enhanced.
Structured brief tactics	When the practitioner uses structured brief tactics s/he does so with skilfulness.
Information and advice	When the practitioner gives information and/or advice s/he does so with skilfulness.

All therapy sessions were digitally audio recorded. Ideally the MITS is designed to rate audiotapes of MI sessions. However, due to the different language proficiencies of group members, all transcripts had to be translated into English. The digital audio files were transcribed and translated by bilingual individuals. The translated transcripts were then checked and edited by the respective therapists for fidelity to the audio recording and to redact any client identifiers. These transcripts were then used for supervision. Additionally, therapists in Satara also had access to each other's Marathi session tapes and the therapists in Goa (conversant in both Konkani and Marathi) had access to both the Marathi and Konkani therapy session tapes. During the initial 10 supervision sessions the MITS scores given by each therapist were discussed in detail with the elaboration of reasons for assigning a particular score. Subsequently, in addition to the MITS score, supervision also included discussion of transcripts annotated by the supervisor (RV). The MITS was simultaneously discussed briefly, but with more focus on the target behaviours where there was a major discrepancy between scores given by two or more therapists. The scores of each therapist were recorded in an Excel sheet for each transcript reviewed in supervision, providing a temporal overview of each therapist's MITS scores and competency acquisition.

The supervision happened in three phases, an *intensive phase*, a *transition phase* and a *maintenance phase*. In the *intensive phase*, RV met weekly with all the therapists in a group supervision format over four months. Therapists who demonstrated a substantial degree of "MI-consistent practice" (score a '1' on the MITS scoring scheme) on each of three randomly selected sessions, moved on to the next phase i.e. *transition phase*. In this phase, the therapist(s) who achieved the required standard supervised the rest of the therapists without RV's input. During the *transition phase*, RV checked some of the session transcripts, led fewer supervision sessions, and undertook individual sessions as and when required with the therapist(s) who was/were supervising the group, thus allowing the local supervisor(s) the opportunity to discuss any difficult issues that arose during group supervision but couldn't be easily resolved. In the final phase (*maintenance phase*), the weekly meetings among the team were led by the local supervisor/s (those therapists who have met the above standards) and they continued until all therapists achieved the required

competencies. During this phase, RV reduced his input to once a month, and focused on discussing with the local supervisors issues of training and supervision, including rating of sessions in order to maintain reliability of ratings among the supervisors.

- b) Peer group supervision: During these sessions, the therapists from Satara and Goa met weekly and discussed issues that had been raised during supervision with RV and issues related to adaptations to the Project MATCH MET manual.

All the supervision sessions were audio recorded and detailed minutes were maintained.

8.2.10 Data collection and management

Each therapist completed the following documents:

- a) Session evaluation form after each therapy session, and
- b) Therapy completion form upon closure of the treatment.

a) The session evaluation form (Appendix 7) was used to document the following:

- 1) The goal of the session,
- 2) The mode of delivery (face to face or phone) and barriers encountered if delivered through phone,
- 3) The duration of the session with an approximate breakdown of time taken to deliver each stage of the session,
- 4) The strategies used, the extent to which these were faithful to the Project MATCH manual and reasons for any modifications made,
- 5) Any challenges that arose during the session, how they were handled, whether information provided in the Project MATCH manual was sufficient to address these challenges and what other sources/information were used to tackle the challenges, and

- 6) Overall opinion of the ease in conducting the session with explanation for the same.

b) The end of treatment evaluation form was used to document the following about the complete treatment journey for each patient:

- 1) The total number of sessions, their duration and frequency,
- 2) Number of sessions delivered on the phone if any,
- 3) Number of weeks over which the intervention was delivered,
- 4) The extent to which the overall phases of intervention were followed, whether they needed alteration and reasons for the alteration, if any,
- 5) Any other intervention strategies used apart from those described in the Project MATCH manual with reasons for using these strategies,
- 6) The extent to which the patient adhered to the treatment expectations (e.g. homework assignments, follow up, etc.) and description of any additional strategies used to address patient adherence,
- 7) Overall clinical response to the intervention,
- 8) Strategy/technique/phase which appeared to contribute most/least to any beneficial effect with reasons for the same, and
- 9) Summary of challenges encountered in using the guidelines of the Project MATCH MET manual, and strategies used to address the challenges.

Data from these forms were collated into a spreadsheet and anonymised for analysis. A record of any adaptations made to the developing CAP manual was maintained with details about the adaptation, reasons for the adaptation and a link to the relevant session transcript.

The following quantitative data was also collected:

- 1) AUDIT score;
- 2) Number of participants screened (directly or after referral by specialist);

- 3) Number of screen positives (i.e. harmful drinkers);
- 4) Number of participants consenting for treatment;
- 5) Number of participants completing treatment;
- 6) Number of sessions attended by each participant; and
- 7) Socio-demographic details of participants entering treatment: age, education, employment status and marital status.

8.2.11 Analyses

Socio-demographic characteristics of the sample and the AUDIT scores were summarised as means and proportions as appropriate. Details of the therapy sessions were summarised as counts, proportions and means as appropriate. Paired t-test was applied to test the difference in overall mean scores on the MITS between the three groups of raters i.e self, peers, and supervisor. The paired t-test is used to compare two means in samples that are correlated. It determines whether the mean of the differences between two paired samples differs from 0, reports whether this mean of the differences is statistically significant, and calculates a range of values that is likely to include the population mean of the differences. It can be more powerful than a 2-sample t-test because, unlike the paired t-test, the 2-sample t-test includes additional variation occurring from the independence of the observations.

Thematic analysis was used to analyse the data from the 'Session Evaluation Form' and 'End of Treatment Evaluation Form'. A coding framework for broad themes to answer the study questions was generated. The broad themes included the challenges and facilitators in delivering the intervention, additional strategies identified in the previous stages of intervention development and that need to be added to the MI 'scaffolding', and any additional components which would need further exploration in subsequent stages of the intervention development process (e.g. controlled drinking as a treatment goal). All data from those two forms were then coded under those broad themes. The most common or significant patterns were then used to generate sub themes that were then used to inform the development of CAP e.g. addition of a medication

related section in the manual because of the medication expectations of patients and/or family members.

8.2.12 Ethical considerations

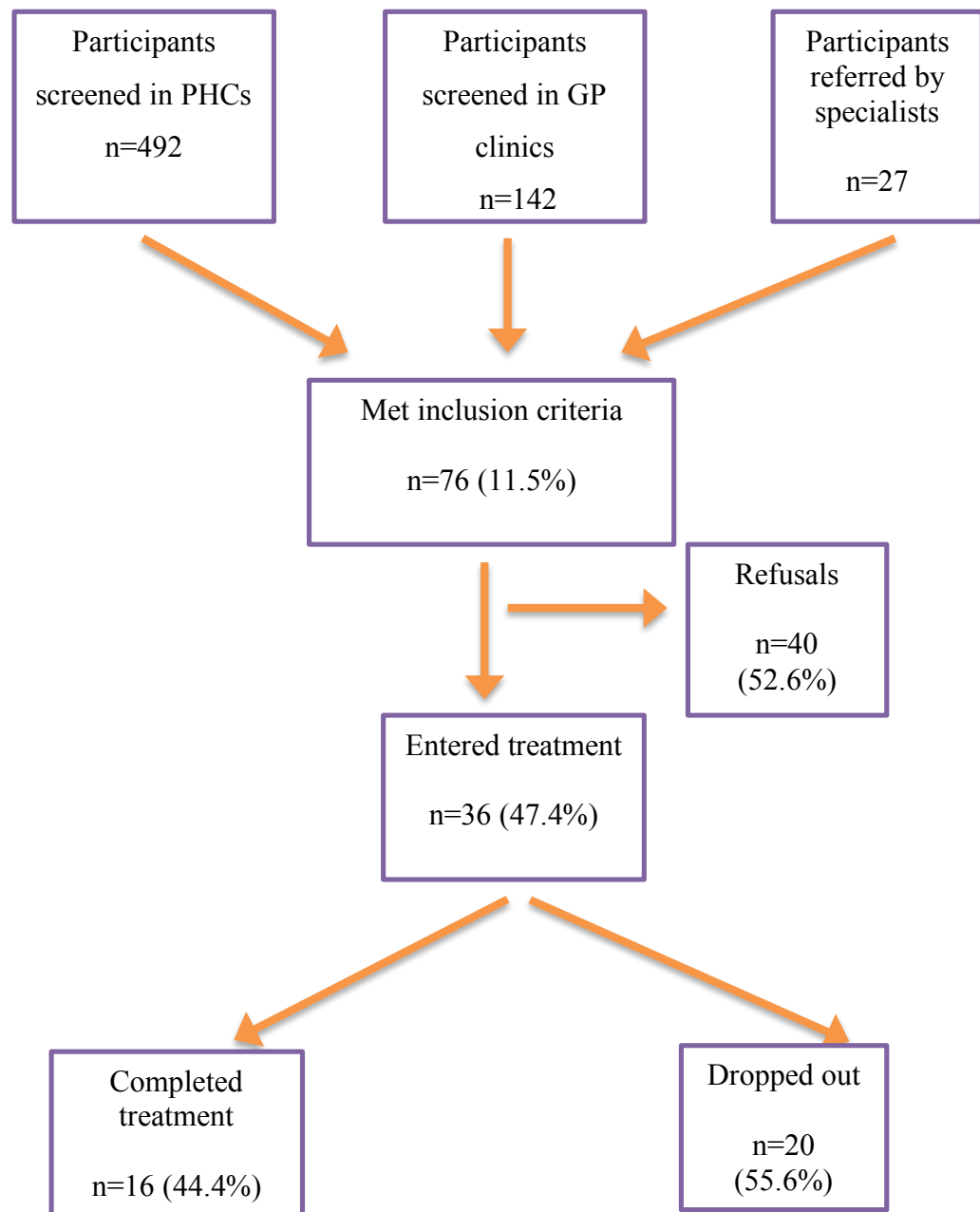
Patients were recruited after they gave informed consent and were free to withdraw from treatment at any stage without their other treatment (non PREMIUM) being compromised in any way. Any patients who were recruited for the case series and had physical health problems were referred to local GP or PHC for treatment. At both sites, any patients who were dependent on alcohol and wanted to stop drinking were advised not to drastically reduce or stop drinking and were referred to the GP or PHC/psychiatric hospital for medically assisted detoxification.

8.3 Findings and resulting adaptations

Due to the nature of the aims of this chapter, this section not only describes the results but also outlines how they informed the development of the CAP manual.

Of the 661 potential participants (492 screened in the PHCs, 142 screened in GP surgeries, 27 referred by specialists), 76 (11.5%) met the criteria for inclusion in the case series. Of these, 36 (47.4%) consented and entered treatment. Of the 40 (52.6%) who did not enter treatment, 30 refused consent and 10 did not attend the first session despite giving consent. Of the 36 who entered treatment, 16 (44.4%) were discharged after completing treatment and the rest dropped out. None of the participants had to be referred out of the treatment because of physical and mental health problems. The flow chart of the treatment pathway is presented in Figure 8.2.

Figure 8.2: Flowchart of patient recruitment for case series



Three of the therapists delivered the intervention to nine patients each, one therapist delivered treatment to five patients, and one therapist delivered treatment to four patients. A total of 78 treatment sessions; a mean of 15.6 per therapist (range 5-25 sessions) were delivered; a minimum of five (6.4%) by one therapist and maximum of 25 (32.1%) by another. The mean number of sessions delivered per patient was 2.2; with mean number of sessions for dropouts being 1.5 and for treatment completers being 2.9. Table 8.5 gives details of the treatment sessions delivered by each therapist.

Table 8.5: Details of therapy sessions delivered in the case series

	Number of patients (n=36) n (%)	OUTCOMES		Number of Sessions n=78 n (%)
		Dropout n=20 (55.6%) n (%)	Completed treatment n=16 (44.4%) n (%)	
Therapist 1	9 (25.0)	6 (66.7)	3 (33.3)	17 (21.8)
Therapist 2	9 (25.0)	4 (44.4)	5 (55.6)	16 (20.5)
Therapist 3	5 (13.9)	1 (20.0)	4 (80.0)	15 (19.2)
Therapist 4	9 (25.0)	5 (55.5)	4 (44.5)	25 (32.1)
Therapist 5	4 (11.1)	4 (100.0)	0 (0)	5 (6.4)
Mean number of sessions (SD)	2.2 (1.3)	1.5 (0.6)	2.9 (1.3)	

The details of supervision are presented in Table 8.6. In all, 26 sessions were rated using MITS. The mean number of sessions rated per therapist were 5.2 (SD 2.4) with a range of 2 to 8 sessions. The overall mean rating by the counsellor while rating his/her own session was 2.4 (SD 0.4). This was similar to the overall mean rating by peers (2.4; SD 0.5) and slightly lower than the rating given by the supervisor (2.5; SD 0.4). There was no significant difference in the overall mean ratings between self and supervisor, self and peers, and supervisor and peers.

Table 8.6: Details of supervision

	Number of sessions rated (n=26) n (%)	Mean score on MITS			Mean (SD)
		Self n=26 (100%) Mean (SD)	Supervisor n=21 (80.8%) Mean (SD)	Peer n=26 (100%) Mean (SD)	
Therapist 1	8 (30.8)	2.3 (0.6)	2.3 (0.8)	2.3 (0.6)	2.3 (0.0)
Therapist 2	2 (7.7)	2.2 (0.2)	2.0 (0.4)	1.8 (0.4)	2.0 (0.2)
Therapist 3	7 (26.9)	2.6 (0.5)	2.6 (0.9)	2.7 (0.5)	2.6 (0.1)
Therapist 4	5 (19.2)	3.0 (0.6)	3.1 (0.9)	3.1 (0.4)	3.1 (0.1)
Therapist 5	4 (15.4)	1.9 (0.4)	2.6 (0.2)	2.3 (0.5)	2.3 (0.4)
Mean (SD)	5.2 (2.4)	2.4 (0.4)	2.5 (0.4)	2.4 (0.5)	2.5 (0.4)

The socio-demographic characteristics of the patients entering treatment are described in Table 8.7. The mean age was 40 years and a predominant proportion was educated (77.8%), employed (88.9%), and married (86.1%). The mean AUDIT score of the participants was 16.8 with a range of 9 to 32.

Table 8.7: Socio-demographic details of patients who entered treatment

Socio demographic variable	Patients (n=36) n (% or range)
Mean age in years (range)	39.7 (19 - 61)
Education	
No formal education	8 (22.2)
Primary school education	5 (13.9)
Secondary School	17 (47.2)
College/University	6 (16.7)
Employment	
Employed	32 (88.9)
Retired/Unemployed	4 (11.1)
Marital status	
Never married/Divorced/Separated	5 (13.9)
Married	31 (86.1)

The following section describes the experiences and challenges faced during delivery of MET according to the Project MATCH manual and solutions proposed to address the challenges; and how all of these informed the development of the CAP intervention/manual.

8.3.1 Structure and content of CAP

a) Number of sessions:

Findings: The Project MATCH MET manual prescribed four MET sessions for all patients. However the Project MATCH MET was designed for dependent drinkers, a more severe form of AUD as compared to hazardous and harmful drinking. It was observed in this case series that for several patients, especially those who entered treatment with well formulated change plans; the therapeutic work reached a saturation point after two sessions. It was also observed that most of the needs of hazardous and harmful drinking patients could be addressed in two sessions but there was a subgroup of patients with greater needs who required more sessions.

Outcome: Based on this observation, it was decided that for CAP one completed session would be the minimum requirement (for obvious reasons), two sessions (mean number of sessions completed in the case series) would be optimum and four sessions would be maximum (as prescribed by Project MATCH MET manual).

b) Structure of sessions:

Findings: The Project MATCH MET manual did not have any guidelines about specific tasks that needed to be completed in each particular session. This level of flexibility of implementation was suitable for experienced practitioners like those in Project MATCH but was difficult for the CAP therapists who were new to MI.

Outcome: It was decided that the CAP manual which was being designed for NSHWs, who would not have even the mental health experience that the therapists in this case series had, would specify the mandatory tasks, to be completed in each session. A checklist of the tasks that would provide the NSHW with a structured framework to follow also supplemented this.

c) Engagement:

Findings: Although the therapists were experienced mental health practitioners, they were new to MI. Furthermore, patients themselves

were not used to a MI style of counselling, and hence the former found it difficult to engage the latter with the use of MI alone. For NSHWs who had no experience of delivering psychosocial interventions it would be equally, if not more, difficult to engage patients using a highly sophisticated MI style.

Outcome: It was decided to develop a Counselling Relationship (CR) manual which would have details about supportive counselling skills (the other core strategy identified in the formative research) like listening skills, open ended questioning etc. This manual was linked to the CAP manual as well as to the depression intervention manual also being developed as a part of PREMIUM.

d) Psycho-education:

Findings: It was observed that patients and their family members had limited understanding of various aspects of AUD and its treatments. Consequently they found it difficult to associate the various bio-psycho-social problems to the heavy drinking. Combined with the lack of understanding about the treatment options available for AUD, this meant that patients with AUD and their family rarely sought any help for the former's drinking problems. From the therapists' perspective, this meant that multiple opportunities for providing psycho-education presented themselves throughout the therapy sessions.

Outcome: To provide need based psycho-education throughout the therapy process it was decided to develop an interactive psycho-educational booklet with extensive pictorial content. This would have enough material to address a range of psycho-educational opportunities that present during the sessions and the stress would be on pictorial content to improve access to clients who had limited or no literacy.

e) Medication related expectations:

Findings: Patients in India, as well as their family members are culturally attuned to being prescribed medications for their health problems, including drinking problems. Hence, the therapists frequently encountered patients and family members who would express a strong

need for medications to treat the former's drinking problem. However, CAP was focussed on harmful drinking for which psychosocial interventions are the only mode of treatment.

Outcome: To help the therapists (and later the NSHWs) to effectively handle medicine related concerns of patients and family members a module was added to the CAP manual. This module informed the therapists on how to address medication related concerns of the patients/family members and also provided details about the medications used in treatment of some types of AUD, to empower the therapists to provide accurate information to the patients/family members.

f) Referral pathways:

Findings: During the course of the case series, the therapists came across many patients having physical co morbidity and high level of dependence on alcohol. Managing such co-morbidity and the medical management of alcohol dependence would be beyond the scope of a NSHW's role.

Outcome: Anticipating a similar situation when NSHWs started delivering CAP to patients and to ensure appropriate referral and management of patients who require specialist help, beyond what could be provided by the NSHW, a module with appropriate referral pathways was built into the CAP manual.

Table 8.8 summarises the themes described above.

Table 8.8: Summary of some challenges and experiences of delivering MET and how they helped develop the CAP intervention

Theme	Challenge/Observation	Solution	Reasons
Number of sessions	For several patients the therapeutic work reached a saturation point after two sessions.	Four sessions were considered as maximum and two sessions were considered as optimum required for treatment completion.	Most of the needs of harmful drinking clients could be addressed in two sessions but there was a subgroup of clients with greater needs who required more sessions.
Structure of session	The therapists who were new to MET found it difficult to deal with the flexibility inherent to MI.	A checklist of the tasks that the NSHW would have to complete would accompany the manual.	This would provide the NSHW with a framework to follow.
Engagement	Difficulties in engagement with use of MI alone as it is a difficult skill to master.	Development of the Counselling Relationship (CR) manual.	Certain subgroups of patients are difficult to engage despite the use of best MI practices.
Psycho-education	Multiple opportunities for providing psycho-education presented themselves throughout the sessions.	To develop interactive psycho-educational booklets with extensive pictorial content.	To provide enough material to address a range of psycho-educational opportunities that present during the sessions. The stress was on pictorial content to improve access to clients who have limited or no literacy.

Theme	Challenge/Observation	Solution	Reasons
Referral pathways	Many patients had physical co morbidity and high level of dependence on alcohol.	A module about appropriate referral pathways for such patients was added to the manual.	To ensure appropriate referral and management of patients who require specialist help beyond what could be provided by the NSHWs.

8.3.2 Additional psychosocial strategies

In the previous stage of the intervention development process, several psychosocial intervention strategies were identified and it was decided that these strategies would be stitched together on a 'scaffolding' of MI as needed. The list of strategies from that list that were used in this case series and the rationale for their use is described in the Table 8.9 below. Following the approach adopted by Project COMBINE (Zarkin et al., 2008) which also aimed to combine strategies from different classes of psychosocial therapies for AUD, after initial engagement with the client in the MI style, additional strategies were used based on the needs of the patient and all these strategies were delivered in a MI consistent way.

Various patients expressed a range of challenges to reducing/stopping their drinking and also in maintaining their reduced/stopped drinking status. They expressed a lack of skills/tools to handle these challenges and hence were unable to tackle their drinking problems successfully. Some of the psychosocial strategies that were identified during the formative phases of the intervention development process described in the preceding steps were used to provide these patients with the necessary skills to deal with these challenges. These psychosocial strategies included a) Problem solving, b) Drink refusal skills, c) Handling urges to drink, d) Handling difficult emotions, and e) Relapse prevention. The rationale for adding these strategies to the core of MI is described in Table 8.9.

Table 8.9: The psychosocial intervention strategies beyond MI used in the case series

Theme	Example	Rationale	Modules
Difficulties in handling life problems	Patients expressed difficulties in handling problems in daily life that lead to increased stress levels and the subsequent drinking e.g. loss of job.	Difficulties in solving problems of daily life leads to increased stress and subsequent drinking of alcohol.	A module on problem solving skills was added to CAP.
Difficulties in handling social situations	<p>Patients reported an inability to handle peer influences as a specific reason for drinking and asked for help to handle the peer influence.</p> <p>Patients also reported that they drink because they feel they can express their emotions only after drinking.</p>	Specific social skill deficits like difficulties in handling peer influences and difficulties in expressing emotions are considered as important reasons for drinking alcohol.	Social skills training requires high level of therapist competence and multiple sessions for delivery. Hence, a intervention module focusing only on two specific components of social skills training was developed, namely drink refusal skills and handling difficult emotions , as these were the most frequently observed skill deficits experienced by patients.

Theme	Example	Rationale	Modules
Difficulties in handling drink related thoughts	Patients reported getting thoughts about drinking and craving for alcohol; and asked for help to tackle the same.	Patients experienced thoughts about drinking and craving for alcohol even after stopping or reducing alcohol intake.	Delivering cognitive restructuring requires significantly higher level of competence and multiple sessions, and hence was excluded during the treatment development workshops. However, considering the felt need during the case series, the clinical team decide to introduce a intervention module focusing only on techniques for handling drinking urges into the CAP manual.
Inability to sustain change	Some patients who had stopped drinking experienced a relapse during the course of treatment.	AUD is a relapsing condition and some patients tend to resume drinking in between sessions in spite of best of interventions	A separate module on relapse prevention strategies was added to the CAP manual.

8.3.3 Barriers to intervention acceptability and feasibility

In the process of delivering MI, the therapists encountered a number of challenges that helped shape the content as well as the delivery of CAP. The barriers experienced are classified below as practical, psychological and cultural barriers.

a. Practical barriers:

Findings: Barriers under this category refer to obstacles that are external to the patient. Examples of such barriers experienced by patients in the case series included lack of time to attend treatment sessions because of their work responsibilities.

Outcome: To overcome such practical barriers to access it was decided to consider two other delivery sites/modes besides delivering CAP in the clinics. Therapists started using telephone calls after patients missed appointments to engage them and to prevent them from dropping out after the missed appointment. The aim of the telephone call was to understand the reason for the missed appointment and to reschedule the appointment. Such telephone conversations were used to maintain engagement with the patients and typically lasted less than five minutes. However, it was decided to take this one step further in the next stage and to use the telephone for delivering CAP for patients who found it difficult to come to the clinic for their scheduled therapy sessions.

Therapists also started doing home visits to deliver CAP for some patients who could not access the PHC because of practical barriers. As the sessions delivered at home were well received by patients and their family members it was decided that this would be further explored in the next step of intervention development.

b. Psychological barriers:

Findings: These were the obstacles that were related to the personal characteristics of the patients seeking treatment. Most of the barriers encountered under this heading were related to the inherent nature of AUD. These included patients believing they did not need treatment for

their AUD as they thought that their drinking was under control and not causing any damage to their life, patients stopping drinking between screening positive and the first session and hence not wanting any further help, and patients attending sessions under the influence of alcohol.

Outcome: Each of these situations resulted in sections being written into the CAP manual explaining how to deal with these commonly encountered challenges. For example, in the situation where patients stopped drinking before the first session and consequently did not feel they needed therapy, the manual has a section which teaches the NSHW how to engage the patient by affirming the positive change (i.e. stopped drinking) but at the same time explaining to him how it is important to learn the skills to maintain the positive change through relapse prevention strategies.

c. Cultural barriers:

Findings: These were barriers posed by the socio-cultural milieu of the patient. One example of such a barrier was the difficulty faced by some patients in keeping to scheduled appointments. It was observed in multiple instances that though appointments were fixed at the patients' convenience, they failed to keep the appointment. One of the reasons behind this problem was the less structured daily schedules in rural Indian communities.

Outcome: One solution to overcome this barrier was to send a SMS reminder about the appointment to the patient. Another way of engaging such patients was through telephone delivered sessions and home visits as described above.

8.3.4 Challenges requiring further exploration in formative work

Besides the challenges described above where changes were made to the developing CAP manual to overcome them, there were two other major challenges that would need further exploration in subsequent stages of the intervention development process. These challenges are described in further detail below:

a) Treatment goal

Findings: The goal of treatment for AUDs has always been a controversial issue. The Project MATCH MET unequivocally emphasises abstinence as the goal of treatment. It also describes the process of discussing the goal of treatment with the client in a MI consistent manner so that this goal is not imposed on the client. However, Project MATCH MET manual describes treatment for patients with alcohol dependence syndrome while CAP is an intervention developed for patients with harmful drinking. In such patients, besides abstinence, controlled drinking may be an equally acceptable and achievable goal of treatment. In addition to this general principle, some patients in the case series themselves specifically expressed a desire to have controlled drinking, rather than abstinence, as a goal of treatment.

Outcome: The therapists extensively discussed this issue at the supervision sessions and Table 8.10 below summarises the content of these discussions. Considering the complexity of the issue it was decided to explore this further in the next stage of the intervention development process.

Table 8.10: Arguments in favour of or against controlled drinking and total abstinence as goals of treatment

Controlled drinking	Total abstinence
Respect for the personal choice and autonomy of the patient who wants to do controlled drinking.	The public health services, where the study was based and CAP eventually delivered, might not support a study in which controlled drinking could be a possible treatment goal.
CAP was being developed for harmful drinkers, in whom controlled drinking can be a realistic goal.	In the rapidly changing cultural landscape of India where there are industry driven efforts to promote permissive drinking, there is a possibility that such a treatment goal might be misconstrued as promotion of drinking.
There is substantial evidence	Difficulties in generalising Western

Controlled drinking	Total abstinence
supporting controlled drinking as a realistic goal of the treatment for AUD.	evidence about controlled drinking to the Indian setting.
	Unavailability of sensible drinking norms for Indian population. Indeed, patients were confusing controlled drinking (with a structured plan) with ' <i>reducing drinking</i> ' or ' <i>drinking only when I want to</i> ' without any structured plan.
	Conflict with the abstinence oriented ethos of one of the agencies delivering CAP.

b) Engagement stance of the therapist

Findings: Fostering independence of the patient through the collaborative stance of the therapist is considered as one of the core components of MI. In the Indian cultural setting, patients expect directive advice from the therapist and the therapist too has been trained and is experienced in giving directive advice to patients. This was observed in the case series too where some of the therapists (who had received clinical training in India) tended to give directive advice and the patients themselves indicated that they wanted that to happen.

Outcome: As the collaborative stance is a key element of MI it was decided to persist with the use of collaborative stance even in the next stage of the intervention development process. It was also decided to use a directive approach in a MI consistent way if the collaborative approach failed to evoke change talk in client. For example, a therapist might say "*Would it be helpful/would you mind if I made some suggestions here?*" and then (if the patient said that it *would* be helpful) go on to do that: "*Do you think that it might be helpful if you told your friends that you had decided to cut down on your drinking? If you told them both that, and also the tactics you were going to use* (such as drinking a non-alcoholic drink every alternative drink, or

drinking at half the rate that everyone else was drinking, or limiting yourself to 2 peps) *it would mean that they would be much less likely to try to persuade you to drink more, and also it would mean that you would be less likely to change your mind, as they would notice that you were not doing what you had said that you wanted to do*"

Or

"Have you thought of making a list of all of these things that you are keen to do but never get around to doing? You could make sure that each of these tasks took up no more than one hour, and then make sure that you completed at least one every day, and then crossed that item off the list: that would make sure that you started a positive spiral where every day you could see that you were achieving something."

However, this is a challenging experience, as being directive in this MI-consistent way is both difficult and different to the way that many therapists in India have been directive in the past; and it was decided that future case work in the next stage of the intervention development process would need to experiment with evolving an engagement stance which could be MI consistent as well as contextually acceptable in terms of the degree of directedness.

8.4 Output

This chapter describes the first attempt in the PREMIUM project to deliver a psychosocial intervention for men with harmful drinking. This was done primarily with the aim of documenting the challenges in delivering the core psychosocial strategy (MI) in an Indian setting and to develop the CAP intervention by weaving other relevant psychosocial intervention strategies to the MI 'scaffolding' using the learning from the case series.

This process led to the development of the first draft of the CAP intervention which was informed by the formative research described in the preceding chapters, and further developed based on the findings of this case series, especially the challenges of delivering MI in an Indian setting. The case series also generated preliminary evidence to suggest that in an Indian setting it is possible to recruit patients with harmful drinking and to deliver to them a MI

based intervention. What we had at the end of this step is the draft of an intervention that was a compilation of evidence based psychosocial intervention strategies held together by a proposed theoretical framework. This approach of compiling psychosocial intervention strategies from a range of psychosocial interventions is informed by the Distillation and Matching model, also called the 'Common Elements' approach (Chorpita et al., 2005). This approach proposes that evidence-based interventions share the majority of their "practice elements" in common with each other and thus a large number of evidence-based interventions can be distilled to a smaller number of common elements. It further states that one can then select and use those distilled practice elements that apply to particular patient characteristics as reported in the literature. One major critique of such an approach is that for a complex psychosocial intervention the whole may be greater than the sum of its parts, and using some of the component strategies in isolation may lead to loss of effectiveness. However, the CAP has a well defined proposed mechanism (described in Chapter 11) and our contention is that the well-defined and manualised structure of the CAP along with on-going quality control mechanisms would overcome such potential limitations. And finally, the best validation of the approach that we followed to develop CAP will be the results of the definitive RCTs that tested CAP and HAP (The intervention for depression developed using the same model). There are reasons to be hopeful about the effectiveness of such an approach as there is emerging evidence of the effectiveness of other interventions developed using this approach (Weisz et al., 2012).

Besides the case series informing the development of the CAP intervention manual it also raised several contextual questions that would need answering in the subsequent steps, and observations that would allow the refinement of the intervention delivery process. These included issues like goals of treatment, and development of procedures to overcome barriers to access to reduce drop out from treatment. Although the high drop-out rates were concerning, they were not much different from drop-out rates usually seen in alcohol treatment services (McKellar et al., 2006). Some factors that are associated with drop-out from drug and alcohol treatment programmes include lower education, younger age, ethnic minority status, lower socio-economic status, lower severity of

alcohol problems, and delayed initiation of treatment after first contact (McKellar et al., 2006; Wickizer et al., 1994). Although most (except the last) of these factors are unmodifiable in the next step of treatment development we decided to implement simple evidence based measures such as offering prompt, convenient appointments, offering reminders and augmenting with telephone contact to enhance treatment retention (Mitchell and Selmes, 2007).

The next step of the intervention development process (Chapter 9) aimed at resolving these contextual questions and refining the CAP intervention while testing the delivery of the intervention using NSHWs (described as 'lay counsellors' from this point onwards).

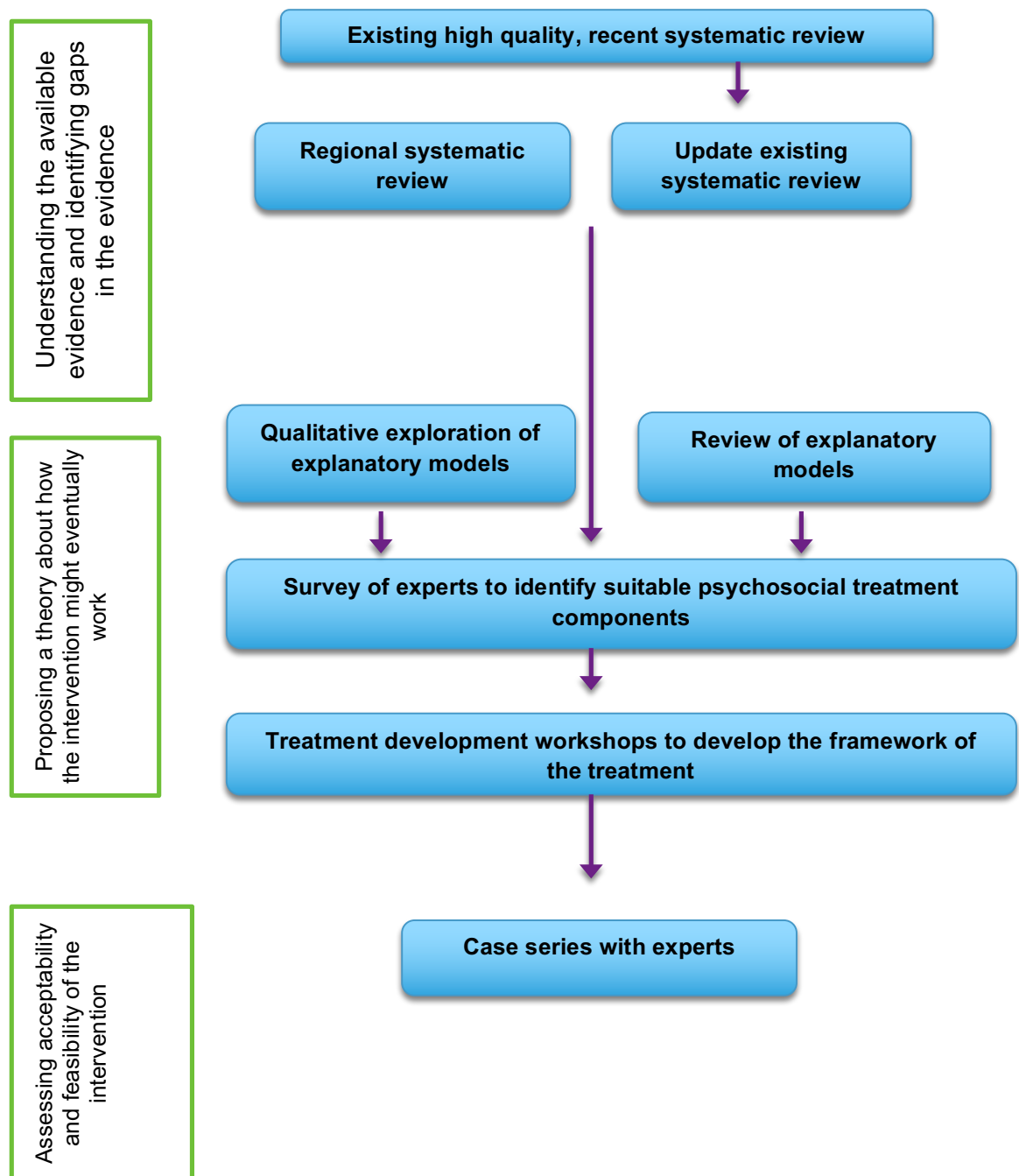
CHAPTER 9: CASE SERIES WITH LAY COUNSELLORS: EXPERIENCES OF DELIVERING CAP^{*}**

9.1 Background

In the previous step of the intervention development process the first draft of the Counselling for Alcohol Problems (CAP) manual was developed and a group of therapists (experienced clinicians) gained competency in delivering it via intensive supervision based on discussions of translated transcripts of their cases. During this process, the manual was revised iteratively based on the experiences from that case series (Fig 9.1).

^{***} Author contribution to the methods: I developed the study design, contributed to the development of data collection tools, contributed to the recruitment, training, selection, and supervision of the counsellors, contributed to the revision of the CAP manual based on incoming data, analysed the data, synthesised the results, and interpreted the findings.

Figure 9.1: Progress of the intervention development process



An important aim of PREMIUM was to bridge the treatment gap for harmful drinking in low resource setting by developing an intervention that could be delivered by lay counsellors. Thus, a crucial step in the intervention development process was to examine the acceptability and feasibility of CAP when delivered by lay counsellors and to further refine the intervention based on this experience. Therefore the overall aim of the step described in this chapter was to test the delivery of CAP by lay counsellors and to use the data collected during that process to further refine the CAP manual to enhance its acceptability and feasibility.

The specific objectives of this step were as follows:

A) Psychosocial intervention development

1. To test the feasibility of and challenges in delivering CAP by lay counsellors,
2. To use the findings of #1 above to inform adaptations to CAP to increase feasibility of delivery by lay counsellors and acceptability to patients,
3. To estimate the preliminary impact of the CAP intervention, and
4. To explore the predictors (e.g. SO involvement) of impact of the intervention.

B) Build competencies of lay counsellors and maintain quality of the intervention delivered by developing and testing procedures for

1. Recruiting and training lay counsellors,
2. Testing competencies of lay counsellors in delivering CAP in primary care settings, and
3. Sustaining and further developing quality of the intervention delivered through on-going supervision.

9.2 Methods

9.2.1 Setting

The socio-demographic profile of Goa has been described in Chapter 1. Goa has one of the better functioning publicly funded healthcare systems in India. The primary healthcare system in India has three tiers, namely Sub-Centres, Primary Health Centres (PHC) and Community Health Centres (CHC). The Sub-Centre is the most peripheral interface between the primary healthcare system and the community and is manned by non-specialist health workers (NSHW) known as Multi-Purpose Health Workers (MPHW). The PHC is headed by a health officer (HO) who is supported by the Medical Officer(s) (MO) and para-medical and other staff to deliver frontline medical services. The HO and MOs usually have a basic medical degree (MBBS). The CHCs, which serve as referral centres for the PHCs, are headed by a HO who is supported by MOs and some specialist doctors. In addition, in remote and inaccessible areas of the state there are Rural Medical Dispensaries (RMD) that are manned by a MO. In Goa there are 5 CHCs, 19 PHCs, 172 Sub-Centres and 29 RMDs. The

case series was conducted in three CHCs (Pernem, Valpoi and Ponda) and eight PHCs (Sanguem, Loutolim, Siolim, Candolim, Bicholim, Sanquelim, Cansarvanem, and Aldona) in Goa. These were purposively selected based on their high caseload to ensure an adequately large universe to screen for men with harmful drinking.

9.2.2 Sample

Adult (>18 years) men attending the participating PHCs/CHCs and satisfying the eligibility criteria were screened by trained 'Health Assistants' using the Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993). It was not possible to screen all eligible men attending the PHC as the flow of patients through the PHC was independent of the screening procedures. This meant that while a patient was getting screened, some patients waiting to see the doctor would complete their consultation and leave the PHC without getting screened. However, the attempt was to screen as many eligible men as possible attending the PHC on any given day. All adult men scoring 12 to 19 on the AUDIT were recruited into the study after obtaining informed consent. The reasons for reducing the cut off score to 12, instead of the WHO recommended 15, have been presented in Chapter 8.

The original AUDIT covers the drinking history over a 12-month period (*"Now I am going to ask you some questions about your use of alcoholic beverages during this past year"*). However, using this version was inappropriate for the purpose of this study as the outcome evaluation was planned to happen at three months post recruitment. Hence, the AUDIT was also adapted to cover a three-month period (instead of a year) to be consistent with the three-month outcome assessment schedule. Such an approach has been used in other studies (Kunz et al., 2004).

Men with active symptoms of co-morbid severe mental disorders like Schizophrenia or Bipolar disorder were excluded from the study as their symptoms could potentially interfere with engagement with the psychosocial intervention. Similarly, men with co-morbid serious physical illness that could prevent engagement with the psychosocial intervention (e.g. stroke) were also excluded from the study.



Image 9.1: Health assistant screening for harmful drinking using AUDIT on a Tablet PC

9.2.3 Intervention

All consenting participants were delivered the manualised CAP intervention as described in Chapter 8. Throughout this case series the CAP intervention was iteratively refined based on the data being collected. This meant that the intervention went through a series of refinements and testing of the refinements as the case series progressed.

The intervention was complemented by an interactive information booklet that was developed as an outcome of the previous step of the intervention development process. The booklet had short sections about CAP, Alcohol Use Disorders (AUD), impact of AUD, strategies to control drinking etc. Considering the literacy level of the participants, the booklet was predominantly graphical. The booklet also had several worksheets such as a 'drink diary, and an 'action plan worksheet' to facilitate intervention delivery. The booklet was developed in English and then translated into the local vernacular languages. Image 9.2 shows a collection of some of the pages from the information booklet.

Image 9.2: Some pages from the CAP information booklet for patients


Impact On Social And Family Life

Family problems:

- Family tension
- Quarrelling and violence
- Missed family functions
- Family members may become anxious, depressed, and may drink excessively themselves
- Children may have behaviour problems and perform poorly in school
- Financial problems and debts

Social difficulties:

- Conflict with colleagues
- Workplace accidents
- Frequent absence from work
- Repeated dismissals from work and long-term unemployment
- Arguments and fights
- Problems with the police
- Loss of friends



Why It Is Important That You Take Charge Of Your Drinking


Unhealthy drinking can contribute to many problems. Stopping or reducing drinking can have many important benefits. Tick the ones that would apply to you.

Reduction in domestic violence <input type="checkbox"/>	Improved financial situation <input type="checkbox"/>	Better physical and mental health <input type="checkbox"/>
Having an active personal and social life <input type="checkbox"/>	Regaining lost social status <input type="checkbox"/>	Reduced mental health problems for other family members <input type="checkbox"/>
Reduced risk of physical injury <input type="checkbox"/>	Developing interest in new enjoyable activities <input type="checkbox"/>	Improvement in work performance, less absenteeism <input type="checkbox"/>

What You Can Do To Control Your Drinking


Some of the skills that a patient aiming for controlled drinking can use are:

Before drinking




- Eat something first.
- Go out later.

While drinking
What to drink



- Drink a long soft drink first.
- Drink pints vs large beers; singles vs doubles; ordinary vs strong beers.

While drinking
How to drink








- Drink in sips, rather than gulps.
- Put the glass down between sips.

Saying 'No' To Drinks

It is useful to be able to say 'NO' when offered a drink. If you have stopped or reduced your drinking it is important to be prepared to handle such situations by using certain simple techniques.

Situations where you might need these techniques:

 <p>Attending a party (either alone or with friends or family),</p>	 <p>You visit friends or family members who drink</p>
 <p>Friends or family members who drink visiting you at home,</p>	 <p>Visit to a bar or a restaurant where alcohol is being served</p>



Bottle of alcohol or drink offered as gift on specific occasions.

9.2.4 Counsellors

CAP was delivered to the participants by lay counsellors trained and supervised by the therapists whose training, supervision and competency achievement is described in the previous chapter (Chapter 8).

a) Recruitment of lay counsellors: Potential lay counsellors had to be persons with the following characteristics to be eligible for selection:

- Have no professional qualification in the field of mental health,
- Be at least 18 years of age,
- Should have completed at least high school education,
- Be fluent in the vernacular languages to be used in the study settings i.e. Konkani, Marathi and Hindi; and
- Have an expressed desire to help people with mental health problems.

The lay counsellors were recruited through advertisements in local newspapers and a local cable television channel. The selection process included an interview in which the applicants a) were asked standardised questions designed to examine characteristics like willingness and ability to be part of a team; and b) had to participate in a brief role-play to test communication and interpersonal skills. In the role-play they had to counsel a 'friend' (actor) who was stressed as she wanted to pursue higher education and her family was forcing her to get married. This was done to test for existing 'soft skills' like 'listening'. Based on the performance in the interview, potential lay counsellors were selected for training in general counselling skills and CAP.

b) Training and selection: The selected trainees then underwent an intensive two week training focused on supportive counselling skills (based on the Counselling Relationship manual), and then training in the two interventions to be used in the PREMIUM programme: CAP and the Healthy Activity Programme (HAP) (intervention for depression developed in the PREMIUM programme). The training had three main components viz didactic lectures, skills demonstrations by tutors, and practice of specific skills through role-plays. The tutors for the CAP component were the therapists who had achieved competency in delivering Motivational Interviewing (MI) in the previous step of the intervention development process (Chapter 8).

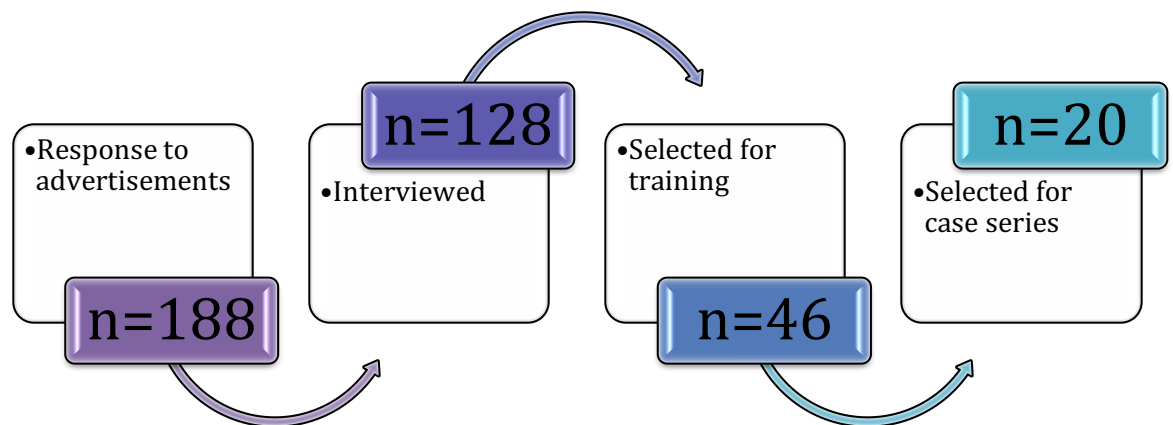
At the end of the training, the trainees were assessed through a) a multiple choice question (MCQ) exam with 50 questions each testing knowledge on the general counselling skills, HAP, and CAP (Appendix 8); and b) role plays using standardised vignettes (an example is provided in Appendix 9) to test general counselling skills and HAP/CAP specific skills. The lay counsellors who scored above the pre-determined cut-off score of 80% on the MCQ exam were then ranked on their competency scores on the role plays measured using the Q-CAP (Quality of CAP) and Q-HAP scales developed specifically to rate CAP and HAP practice respectively; and the former is described in detail below. The 'graduates', based on these outcomes, were invited to become counsellors on the PREMIUM programme.



Image 9.3: Classroom training of the counsellors by the author of the thesis.

A total of 188 applicants responded to the advertisements and 128 were shortlisted to be interviewed by the therapists. Following the interview, 46 prospective lay counsellors were invited for and completed the classroom training. Of the 46 prospective lay counsellors who completed the training, 20 were selected for the case series (field training) (Fig. 9.2). One person dropped out shortly before the case series and hence a total of 19 prospective lay counsellors actually entered the case series. On average, the prospective lay counsellors entering the field training were 28.2 (SD 8.5) years of age with 15 years of education (70.6% were graduates and the rest had completed the equivalent of A levels); and sixteen were female. None of them had any specialist mental health training and the graduates had one of the following degrees: Bachelor of Arts (Geography, English literature, Hindi and Sociology), Bachelor of Commerce, Bachelor of Science (Biotechnology, Chemistry), and Diploma in Pharmacy.

Fig 9.2: Lay counsellor recruitment and training



c) Supervision: The therapists (the author of this thesis and BC) from the case series, who were now deemed to be competent to deliver CAP, supervised the lay counsellors. Supervision of the counsellors happened individually and in groups.

i) Group supervision happened in a day-long meeting conducted every week. The supervision session was facilitated by the therapists and involved the reviewing of individual lay counsellor's recordings of a recent session. The therapist paused the tape at regular intervals and provided feedback on the counsellor's skills. After listening to the complete tape the lay counsellors and the therapist rated the quality of therapy delivered using Q-CAP (Appendix 10). Once everyone had finished scoring the recording, the therapist would first encourage the lay counsellors to share with the group their rating on each item and their reasons for that rating. The therapist would then present his or her rating and rationale for that rating on each item. Areas of skill deficit that were identified were then demonstrated and practiced through role-plays. In addition to reviewing individual's recorded sessions, the lay counsellors were also provided with an opportunity to discuss questions related to the intervention delivery and the challenges encountered by them in using the CAP manual. On average two counsellor sessions were listened to, scored and discussed each week. The 19 counsellors were placed in 11 PHC/CHCs and each PHC/CHC

had one primary counsellor. In group supervision, priority was given to session tapes of the 11 primary counsellors and this led to the tapes of only 17 counsellors being listened to and rated in group supervision. However for individual supervision (described below) an equal opportunity was provided to all 19 counsellors.

ii) Individual supervision was conducted either face-to-face or over telephone or through Skype. In the on-site face-to-face supervision, the therapists would sit in the sessions conducted by the lay counsellor. The counsellors would then receive immediate and specific feedback on their performance. Individual supervision sessions conducted over the phone or Skype involved listening to audio-recorded sessions with the lay counsellor then receiving feedback on their performance.



Image 9.4: A counsellor delivering the CAP intervention in the PHC

9.2.5 Procedures

Patients who screened positive on the AUDIT were invited to participate in the case series by the Health Assistant after the patients' consultation with the

PHC/CHC doctor. After provision of written and verbal information about the case series, consent was sought for participation. After consent was obtained, the Health Assistant collected the baseline socio-demographic and outcome data (Described below).

After the baseline data was collected the participant was introduced to the counsellor who then took over further management i.e. delivery of CAP. Participants were discharged after receiving the maximum number of stipulated sessions of CAP (i.e. four sessions) or completing treatment goals in fewer sessions. Any participant missing three consecutive scheduled sessions was considered as a treatment drop out. However, participants who re-engaged at any point during the case series were offered the opportunity to continue from the last session.

Outcome data was collected at three months post-enrolment. An independent team of community based research workers, who had no contact with the PHC/CHCs, carried out outcome assessments. The intervention and research teams did not have any interactions during the case series and both teams were based in separate physical locations with independent administrative management. A separate set of research workers conducted the qualitative in depth interviews (IDI) and focus group discussions (FGD). IDIs were conducted until data saturation was reached.

All qualitative interviews were audio-taped; the recorded interviews were transcribed verbatim and translated into English. Subsequently, the reflective notes about the interviews and field notes written by the interviewers were also attached to the main text of the interviews. All quantitative baseline and outcome data was collected electronically using tablet computers. The data was remotely uploaded as a CSV (comma separated values) file on the main data server running online using the customized STAR (Sangath Tool for Advanced Research) software program developed for Sangath. The data was GCP (Good Clinical Practice) compliant i.e. there was a date- and time-stamp for the original data entry, and an audit trail documenting any subsequent changes was maintained. The intervention process data (e.g. type of session) and therapy quality data (Q-CAP scores) were collected in paper and pencil form, and these

were then manually entered and stored as CSV files using STAR. Access to data was password protected at multiple levels. All digital recordings were stored in secure, password-protected folders.

9.2.6 Data

1) Quantitative data

- a) AUDIT score measured during screening;
- b) Socio-demographic data-age, education, employment, marital status etc. at baseline;
- c) Treatment details-number of sessions, duration of sessions, whether significant other (SO) present etc. during the course of the treatment;
- d) Outcome tools: Several outcome tools were examined for suitability for PREMIUM and they are summarised in Table 9.1. We needed one tool each to measure drinking patterns and impact of drinking. The requirements were for the tools to be simple, easy to administer, relatively short, and preferably validated or used in India. Based on these criteria, the TLFB and SIP were selected for the case series. We did not select Quantity-Frequency (QF) Index because it did not give any indication of variable drinking patterns, especially those which involved heavy episodic drinking (Sobell, 1995). We did not select the Drinking Self-Monitoring Log (DSML) as self monitoring does not yield retrospective drinking data and compliance with self monitoring instructions is generally not good (Sobell, 1995). We did not select Form 90 as it takes 40–60 minutes to obtain 90 days of drinking and related information. Finally, we selected the Short Inventory of Problems (SIP) as it had good psychometric properties but was considerably shorter than the alternatives i.e. Addiction Severity Index (ASI), Drinker Inventory of Consequences (DrInC), and Alcohol Problem Questionnaire (APQ).

The PHQ-9 was selected in the depression arm of the PREMIUM programme because of its psychometric properties, ease of administration, and extensive experience of its use in India. To maintain consistency with the depression arm of the programme PHQ-9 was also selected for the AUD arm. Furthermore, as depression is the most

common psychological comorbidity in AUD we decided to focus on it and not on the other psychopathologies that are not as common.

Table 9.1: Outcome assessment tools to measure quantity/frequency and impact of drinking

Standardized tools	Short Description	No. of Items & Sub-scales
Quantity and Frequency of Alcohol consumption		
Quantity-Frequency (QF) Index (Sobell, 1995)	Retrospective estimates of average daily consumption and the average frequency with which consumption occurs.	3-items
Drinking Self-Monitoring Log (DSML) (Sobell, 1995)	Asks people to record their drinking at about the same time as it occurs.	Variable; based on number of days (usually between 30 days to 1 year)
Alcohol Timeline Follow Back (TLFB) (Sobell, 1995)	Calendar-based form in which people provide retrospective estimates of their daily drinking, including abstinent days over a specified period of time ranging up to 12 months prior to the interview. Memory aids (real life events, personalized data on programs etc.) are used to enhance recall.	Variable; based on number of days (usually between 30 days to 1 year)
Form 90 (Miller, 1994)	Collects daily drinking information for 90 days prior to the last drink. Form 90 also collects data on other aspects of clients' functioning (e.g., use of drugs; experience with medical and psychological treatments; lifestyle activities such as work, school involvement, and religious participation).	58 items + 90 days calendar

Impact of drinking		
Addiction Severity Index (ASI) (Fureman, 1990)	Assessment and outcome measurement. 30 day & lifetime alcohol use, drug use, medical problems, psychiatric problems, family/social problems, employment, and legal problems.	200-items, seven subscales
Drinker Inventory of Consequences (DrInC) (Miller, 1995)	Measures adverse consequences of alcohol abuse in five areas: Interpersonal, Physical, Social, Impulsive, and Intrapersonal. Each scale provides a lifetime and past 3-month measure of adverse consequences, and subscales can be combined to assess total adverse consequences.	50-items, five subscales
Alcohol Problem Questionnaire (APQ) (Williams, 1994)	Measures alcohol-related problems, it does not include dependence items, but covers eight problem domains: friends, money, police, physical, affective, marital, children, and work. All questions relate to the past six months.	44 items, eight subscales
Short Inventory of Problems (SIP) (Kiluk, 2013)	Shortened version of the DrInC. Measures physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol and drug consumption. All questions relate to the past one month.	15 items

- a) Time Line Follow Back (TLFB), Short Inventory of Problems (SIP) and Patient Health Questionnaire (PHQ 9) (Table 9.2) at baseline and 3 months post recruitment.

The TLFB (Appendix 11) is one the most commonly used method for evaluating retrospective self-report estimates of daily drinking, in clinical practice as well as research. It can be used as a self-completion tool or administered by a clinician/researcher using a paper and pencil version or electronically. It can be used to gather information about drinking up to 12 months in the past. The TLFB is a calendar method to collect data about quantity and frequency of drinking and various memory aids are used to enhance recall (e.g. special dates). The TLFB has high test-retest reliability and concurrent validity has been established in various types of AUD (Sobell and Sobell, 1992). The TLFB has been used in India in previous research (De Sousa and De Sousa, 2008). In the case series the TLFB was used to collect data about drinking in the past two weeks and was used to calculate the total amount of alcohol (gms) consumed in two weeks.

The Short Interview of Problems (SIP) (Appendix 12) is the shortened version of the Drinker Inventory of Consequences (DrInC), a reliable and valid self-administered, 50-item questionnaire developed for Project MATCH to measure adverse consequences of AUD (Kiluk et al., 2013). The SIP can be used in clinical and research settings as an outcome measure. Subscales of the SIP measure adverse consequences of drinking on physical health, social responsibility, intrapersonal functioning, interpersonal, and impulse control domains; and the scores on the sub scales can be combined to assess total adverse consequences. The two versions of SIP measure adverse consequences in the past 3 months (SIP-2R) or Lifetime (ever) (SIP-2L), and for the purpose of PREMIUM the former was used.

The PHQ-9 (Appendix 13) is a short self-report tool used for screening, diagnosing, and measuring the severity of depression using the DSM-IV

depression diagnostic criteria. The scoring of the PHQ-9 takes into account the presence and frequency of the symptoms. The PHQ-9 has been validated in primary care setting (Spitzer et al., 1999) and the translated Konkani version has been used in Goa in previous studies (Patel et al., 2008).

The availability of data for these three outcomes varied as the outcome tools were introduced in the case series in a phased manner.

Table 9.2: Summary of outcome tools used in the case series

Instrument	Description	Outcome	Utility and Validation in India
TLFB	Calendar tool supplemented by memory aids to obtain retrospective estimates of daily drinking over a specified time period that can vary up to 12 months from the interview date. It can be used to generate a range of outcomes like per cent days of heavy drinking (PDHD) and days of heavy drinking.	Alcohol consumed in past two weeks (gms).	Validated instrument (Sobell and Sobell, 1992) and used in India (De Sousa and De Sousa, 2008).
SIP	15-item test that measures physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol and drug consumption. Respondents indicate whether each item occurred in the previous 3 months and get scored on a scale of 0 to 3 based on how frequently it occurred. A higher score indicates more severe alcohol related problems.	Physical, social, intrapersonal, impulsive, and interpersonal consequences of alcohol consumption.	Validated instrument (Alterman et al., 2009) and used in India (Bowen et al., 2006). Translated into Konkani using a protocolised translation and back translation method followed by piloting for language.
PHQ-9	9 item diagnostic instrument which scores each of the 9 DSM-IV criteria for depression on a scale of 0 to 3 based on how frequently they occur. A score of 5 and above on PHQ 9 indicates depression.	Severity of symptoms of depression.	Validated in primary care setting (Spitzer et al., 1999) and Konkani version used in Goa (Patel et al., 2008).

- e) Process indicators: This included data like number of people screened, number of patients who screened positive, number of screen positive who consented to treatment, number of patients who entered treatment and completed it, number of drop outs, etc.; and
- e) Q-CAP (Appendix 10): The ongoing assessment of the quality of the intervention being delivered increase scientific confidence in the impact of the intervention on the measured outcomes. This includes treatment differentiation (did the counsellors only deliver the target treatment and not other treatments), treatment competency (did counsellors maintain the competencies acquired in training), and treatment adherence (delivery of the treatment components as intended) (Borrelli, 2011). The assessment of quality of the treatment delivered should include the assessment of adherence to intervention components and competence to deliver the treatment in the manner specified (e.g., client centered counseling). As CAP was a new treatment which incorporated active strategies from various psychosocial interventions, using an existing quality assesment tool from other projects (e.g. Project MATCH or UKATT) would have led to inadequate coverage of the intervention components.

Hence, the Q-CAP was developed specifically for evaluating the quality of therapy delivered and was also used to track the competency of lay counsellors delivering CAP. The Q-CAP was developed based on the Motivational Interviewing Target Scheme 2.0 (MITS 2.0) (<http://www.motivationalinterviewing.org/motivational-interviewing-target-scheme-mits-20>) described in Chapter 8 and used in the case series with the therapists to measure fidelity to MI techniques. An international expert (Richard Velleman, who was the supervisor in the case series with the therapists) was consulted to determine how the MITS could be adapted to the CAP intervention. The therapists and the international expert then piloted the draft Q-CAP that was developed after adapting the MITS. This involved all of them independently rating the same CAP therapy sessions until there was a high level of agreement on the items of the scale. The Q-CAP was designed in a manner to make it simple to

use (i.e. through simplification of technical terms) and also covered the non-MI components of CAP (e.g. CBT techniques like 'handling difficult emotions'). The draft final scale had two subscales, namely Treatment-Specific Skills (TSS), and General Skills (GS). The TSS included items specific to the MI core of CAP like 'Independence' ('Seeks to enhance patient's sense of control and freedom of choice') and 'Navigation' ('Manages the conversation such that discussion of the drinking behaviour change remains the focus without causing resistant behaviour') and items specific to the other psychosocial strategies e.g. drink refusal skills. The GS included items that form the bedrock of good supportive counselling like 'Empathy' ('Attempts to demonstrate accurate understanding; normalizes patient's experiences') and 'Collaboration' ('Conveys words/actions that therapy is collaborative, in contrast to the counsellor being in charge, where the patient is an active participant'). Each item on the scale can be rated on a 5-point Likert scheme where 0 represents 'not done' and 4 is 'excellent'. Some items can be rated as 'Not applicable'. These are items that are not applicable to all sessions and depend on circumstances e.g. 'Involves SO'.

A high internal consistency has been demonstrated between TSS and GS subscale items, using expert ratings (TSS $\alpha=0.867$; and GS $\alpha=0.896$) and peer ratings (TSS $\alpha=0.858$; and GS $\alpha=0.828$) (Singla et al., 2014). Inter-rater reliability, based on random mean pair comparisons of peer ratings for the Q-CAP, has shown moderate values for intra class coefficients (ICC) estimates for TSS (ICC=0.608) and GS (ICC=0.622) (Singla et al., 2014).

2) Qualitative data

a) Session evaluation (Appendix 14): This data were used to inform further adaptations to the developing manual. Data were collected about the following:

- Challenges in conducting phone sessions or home visits,
- Strategies used in order to deliver the intervention and difficulties in delivering them,

- Additional strategies/techniques which were not in the CAP manual but were used and reasons for using them,
- Counsellors' experience of involving SO in treatment, and
- Any other barriers faced in delivering the session and how these were handled.

b) End of treatment evaluation form (Appendix 15): Data were collected about the following:

- Reason for discharge (e.g. planned, drop out etc.),
- Overall response of the patient to the intervention (e.g. no change, partly improved etc.),
- Strategies from the manual that were perceived to be the most helpful with reasons, and
- Barriers to successfully delivering the intervention with details.

c) In depth interviews (IDIs) with patients were conducted by trained researchers at the end of treatment, to examine their perception of their own clinical condition and to assess their experiences of the CAP intervention (Appendix 16). IDIs were conducted with treatment completers as well as those who dropped out of treatment. The following data were collected:

- Changes in health status since starting CAP and attribution of the change (if any) to CAP,
- Experience of the counselling process,
- Challenges experienced during counselling,
- Acceptability of the frequency and duration of the treatment,
- Acceptability of the various delivery methods (PHC based, home based and telephonic),
- Acceptability of the information booklet,
- Facilitators to completing treatment (to treatment completers),
- Barriers to completing treatment and possible solutions (to treatment dropouts).

d) Focus group discussions (FGDs) were conducted with the lay counsellors mid-way through the case series and at the end of the case series to review

their experiences of delivering the CAP intervention (Appendix 17). Data were collected about the following:

- The experience of working in a primary care setting,
- The experience of delivering CAP and the challenges faced,
- The experience of using the various delivery modes/sites (PHC delivered, home delivered and telephonic),
- The experience of using the information booklet, and
- The experience of supervision.

e) IDIs were conducted with the therapists to review their experiences of supervising the lay counsellors (Appendix 18). Data were collected about the following:

- Their observations about the lay counsellors working in a primary care setting,
- Delivering CAP and the challenges faced, the use the various delivery modes/sites (PHC delivered, home delivered and telephonic), and
- The experience of supervision.

f) IDIs were conducted with SOs of the patients entering treatment to understand their perspective about the intervention (Appendix 19). Data were collected about the following:

- Changes in health status of the patient since starting CAP and attribution of the change (if any) to CAP,
- Acceptability of the various delivery methods (PHC based, home based and telephonic), and
- Acceptability of the information booklet.

Table 9.3 describes how the various data in the case series were collected.

Table 9.3: Procedures for data collection in the case series

Data	Mode of collection	Collected by	Time point for collection
AUDIT	Questionnaire	Health Assistant	Baseline
Socio-demographic data		Health Assistant	Baseline
Intervention details	Session evaluation form	Counsellor	Throughout treatment
	End of treatment evaluation form		End of treatment
TLFB	Questionnaire	Health Assistant	Baseline
		Research worker	3 months post enrolment
SIP	Questionnaire	Health Assistant	Baseline
		Research worker	3 months post enrolment
PHQ 9	Questionnaire	Health Assistant	Baseline
		Research worker	3 months post enrolment
Process indicators	Screening register	Health assistant	Baseline
Q-CAP	Quality assessment tool	Counsellors, supervisor	Throughout case series
Acceptability and feasibility of delivering CAP	FGD with counsellors	Research worker	Midway and end of case series
	IDIs with supervisors, patients, and SOs		At the end of the case series

9.2.7 Analyses

Process indicators of the screening, treatment process and competency evaluation were presented as proportions and means as appropriate. Socio-demographic characteristics of the sample and the AUDIT scores were summarised as means and proportions as appropriate. The mean pre and post scores on SIP and PHQ-9 and total alcohol (gms) consumed in past two weeks were compared using the paired t-test. The paired t-test is used to compare two means in samples that are correlated and hence is suitable for studies with a 'before-after' design.

The hypothesised predictors (independent variables) of treatment outcomes were converted into binary variables viz age (≤ 40 years, > 40 years), marital status (never married/post-marital, married), educational status (literate, illiterate), employment status (employed, unemployed), treatment completion (dropped out, completed), and presence of SO at one or more sessions (yes, no). The treatment outcomes (dependent variables) too were converted into binary variables viz abstinence (yes, no), SIP score (static/increased or reduced) and PHQ-9 score (static/increased or reduced). Univariate analyses were conducted to examine the association of each of these independent variables with the dependent variables. Logistic regression was then conducted to examine the independent relation of these various predictors and treatment outcomes. All variables significant at $p < 0.1$ on univariate analyses were then added to a multiple logistic regression model and adjusted for baseline AUDIT score. Logistic regression is a predictive analysis and is used to explain the relationship between a dependent binary variable and one or more independent variables. I selected logistic regression as the appropriate regression analysis for this study as the dependent variables were binary.

Mean scores (and range) on the TSS and GS sub scales of the Q-CAP were calculated separately for the supervisors (therapists), the counsellor whose session was reviewed (self) and the rest of the counsellors (peers). Mean sub-scale scores were calculated by dividing the total of all item scores in that scale by the number of items that had been scored to arrive at a mean scale score. The denominator took into account "Not Applicable" as a potential option. All the peer ratings were then averaged to get a mean peer rating. Mean 'self' ratings

and 'supervisor' ratings were calculated in a similar manner. Paired t-tests were then calculated to assess differences between the raters on mean subscale scores.

Thematic analyses were used to analyse the data from the 'Session Evaluation Form', 'End of Treatment Evaluation Form', IDIs and FGDs. The analysis was a combination of deductive and subsequently inductive strategies. A coding framework for broad themes to answer the study questions was generated. All data from the 'Session Evaluation Form', 'End of Treatment Evaluation Form', IDIs and FGDs were then coded under those broad themes. Initially, a set of pre-determined codes (e.g. challenges to home visits) were developed based on the study aims and were deductively applied to the data. Subsequent analysis involved inductive generation of new codes from raw data (e.g. 'acquisition of competencies'). These codes were used to generate a new coding template, which was then applied to the remaining interviews. Codes were then compared with each other for similarity in meaning. Similar codes were collapsed into inclusive categories and clusters of related codes were organised under other codes, forming hierarchies. The most common or significant patterns were then used to generate themes that were then used to inform the further refinement of CAP. The themes were supported by excerpts from transcripts to demonstrate that themes were as close to the data as possible and reflected the words used by the participants themselves.

9.2.8 Ethical considerations

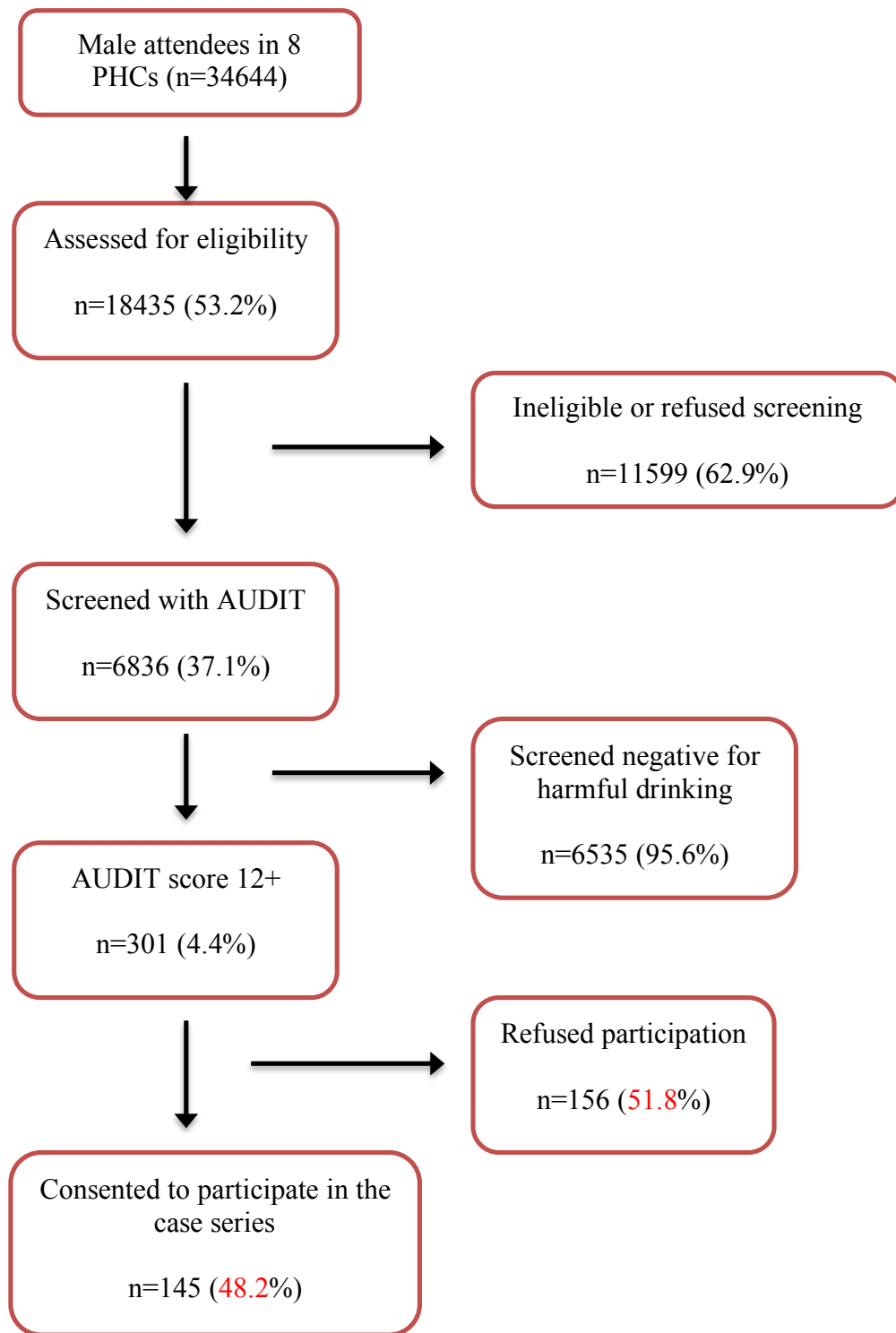
Any patients who were dependent on alcohol and wanted to stop drinking were advised not to drastically reduce or stop drinking and were referred to the de-addiction centre for medically assisted detoxification. Eligible patients were given verbal and written information about the CAP intervention and the research process (e.g. outcome evaluation) by the health assistant. The patients were then given an opportunity to further discuss the project and to ask any questions. The information sheet and consent form were read out to illiterate participants and they were invited to express verbal consent, and an impression of the thumb print was taken on the consent form, witnessed by a family member.

9.3 Results

9.3.1 Recruitment of participants

Of the 34,644 adult men who attended the PHCs for the duration of the screening (6 months) 18435 (53.2%) were screened for eligibility. Of these, 11,599 were either ineligible for screening (n=11505) (for a range of reasons e.g. age <18 years, could not speak the local language) or refused screening (n= 94). The remaining 6836 (37.1%) were screened with the AUDIT. Of those, 301 (4.4%) screened positive for harmful drinking (AUDIT 12-19). 156 (51.8%) refused to participate or were not included in the study and 145 entered the case series (Fig 9.3). Reasons for refusal or non inclusion included the following: Patient did not specify any reason or health assistant could not find the patient after his consultation with doctor (n=73; 46.8%), patient not interested in the intervention (n=40; 25.6%), patient did not have time (29; 18.6%), baseline assessment tools in were not available in Hindi in the initial stage of the case series and hence Hindi speaking patients could not be recruited (n=6; 3.8%), patient was admitted in the PHC after consultation with doctor (n=3; 1.9%), patient expressed an inability to participate without permission from family (n=2; 1.3%), patient was already receiving treatment for AUD from a psychiatrist (n=2; 1.3%), and patient confirmed that he would not reside in the PHC catchment area for entire duration of the intervention delivery and outcome evaluation (n=1; 0.6%).

Fig 9.3: Process and monitoring flow chart for the case series



9.3.2 Sample description

The men who entered treatment had a mean age of 42.1 years (SD=12.4), and predominantly were married, literate and employed. The mean AUDIT score of those who entered the case series was 15 (SD 2.3).

Table 9.4: Socio-demographic profile of participants in the case series

Variable	Harmful drinkers n=145 (62.8%) Mean (SD) or n (%)
Mean age (SD)	42.1 (12.4)
Marital status	
Never married	30 (20.8)
Married	114 (79.2)
Education	
Literate	96 (66.7)
Illiterate	48 (33.3)
Occupation	
Employed	123 (87.9)
Unemployed	17 (12.1)
Mean AUDIT score (SD)	15 (2.3)

9.3.3 Intervention delivery

78 (53.8%) patients dropped out and the rest completed treatment (n=67; 46.2%). The mean number of sessions completed was 1.9 (SD 1.1). The mean number of sessions completed by treatment completers was 2.9 (SD 0.9), which was significantly ($p<0.001$) higher than in dropouts [1.1 (SD 0.4)]. There was no significant relationship between age, marital status, education or baseline AUDIT score and dropout from treatment. Employment status was a significant predictor of dropout from treatment: unemployed patients were significantly more likely to complete treatment compared to those who were employed (Table 9.5). On multivariate analysis none of these factors significantly predicted treatment completion although employment status as an independent predictor of dropout from treatment tended towards significance (OR 3.1; 95% CI 1.0-9.9; $p=0.05$)

All patients entering the case series received the first session. 73 (50.3%) received 2 sessions, 40 (27.6%) received 3 sessions, and 23 (15.9%) received

all 4 sessions. Details of the various sessions are described in Table 9.5. The mean duration of sessions ranged from 27-31 minutes. Sessions were predominantly delivered in the PHCs, followed by the patients' homes. Telephone delivery of the intervention was rare. SOs accompanied approximately around a quarter of the patients, primarily in sessions two and three. None of the participants had to be referred out of the treatment because of physical and mental health problems.

Table 9.5: Comparison of treatment completers and dropouts

Variable	Treatment drop outs n=78 (53.8%) Mean (SD) or n (%)	Treatment completers n=67 (46.2%) Mean (SD) or n (%)	p value
Mean age	41.3 (12.1) mv=3	43.1 (12.8)	0.38
Marital status			
Never married or post marital	20 (66.7)	10 (33.3)	0.1
Married	57 (50.0) mv=1	57 (50.0)	
Education			
Literate	52 (54.2)	44 (45.8)	0.8
Illiterate	25 (52.1) mv=1	23 (47.9)	
Occupation			
Employed	71 (57.7)	52 (42.3)	0.03
Unemployed	5 (29.4) mv=2	12 (70.6) mv=3	

Variable	Treatment drop outs n=78 (53.8%) Mean (SD) or n (%)	Treatment completers n=67 (46.2%) Mean (SD) or n (%)	p value
Mean baseline AUDIT score	15.0 (2.3)	15.0 (2.4)	0.9

Table 9.6: Details of CAP sessions

	Session 1	Session 2	Session 3	Session 4
	Mean (SD) or n (%)	Mean (SD) or n (%)	Mean (SD) or n (%)	Mean (SD) or n (%)
HARMFUL DRINKERS				
Mean duration in minutes (SD)	26.9 (15.0)	31.4 (13.5)	29.9 (9.4)	29.0 (9.5)
Delivered at:				
PHC	145 (100.0)	53 (72.6)	29 (72.5)	19 (82.6)
Patient's home	0 (0)	18 (24.7)	9 (22.5)	4 (17.4)
Telephone	0 (0)	2 (2.7)	2 (5.0)	0 (0)
Significant other present	20 (15.8)	16 (22.9)	8 (22.9)	1 (4.6)
mv	18	3	5	1

mv-Missing values

9.3.4 Quality evaluation

42 randomly selected sessions were reviewed and rated in supervision during the course of the case series. Of the 19 counsellors, sessions of 17 counsellors got reviewed during supervision. The proportion of sessions that were reviewed is as follows: Session 1 (n=21, 50%), Session 2 (n=7, 16.7%), Session 3 (n=7, 16.7%), and Session 4 (n=7, 16.7%). Table 9.7 describes the mean treatment-specific and general skills scores by supervisor, self and peers, and compares the differences in scores by each of these raters. The counsellor whose session tape was reviewed rated himself/herself significantly ($p < 0.05$) higher than the supervisor or peers on the TSS subscale. There was no significant difference between the supervisor and peers on the scores that they gave on the TSS subscale. The three groups of raters (self, peers, supervisor) did not differ significantly on how they scored the sessions on the GS subscale.

Table 9.7: Competency evaluation of counsellors-Mean Differences between Expert, Self and Peer Ratings

	Treatment Specific Skills (TSS) (n=42)	General Skills (GS) (n=42)		TSS Mean Difference (95% CI)	p	GS Mean Difference (95% CI)	p
	Mean (Range)	Mean (Range)					
Self Rating	2.06 (1.07-2.59)	2.35 (1.55-2.85)	Self vs. Supervisor	-0.3 (-0.51--0.09)	0.01	-0.18 (-0.39-0.01)	0.06
Supervisor Rating	1.75 (0.96-2.42)	2.16 (1.25-2.8)	Peer vs. Supervisor	-0.11 (-0.28-0.04)	0.14	-0.08 (-0.2-0.03)	0.14
Peer rating	1.87 (0.95-2.39)	2.25 (1.45-2.66)	Self vs. Peer	-0.18 (-0.36- -0.01)	0.04	-0.1 (-0.24-0.04)	0.14

9.3.5 Outcome evaluation

For the primary drinking outcome (TLFB), data were available at follow up in 92 (63.5%) participants and mean follow up interval was 15.3 (SD 6.8) weeks. Follow up data on the SIP were available for 88 (60.7%) participants and for PHQ 9 it was available for 76 (52.4%) participants. Education, employment status, and baseline AUDIT score were not associated with non-completion of primary outcome (TLFB). Older age, being married, and treatment completion predicted completion of primary outcome evaluation (Table 9.8). However on multivariate analysis only treatment completers were significantly more likely to also complete primary outcome evaluation (OR 3.2; 95% CI 1.5-6.9; $p < 0.002$).

The socio-demographic predictors of completion of the other outcomes were as follows. Compared to those whose follow up data was not available, PHQ data was available at follow up in older men (42.1 [13.6] vs. 42.2 [11.4]; $p = 0.9$), in those with higher AUDIT score (14.8 [2.1] vs. 15.1 [2.5]; $p = 0.5$), higher proportion of employed than unemployed [65 (52.9%) vs. 8 (47.1%); $p = 0.7$], significantly higher proportion of married than unmarried [66 (57.9%) vs. 10 (33.3%); $p = 0.02$], and in higher proportion of literate than illiterate [51 (53.1%) vs. 25 (52.1%); $p = 0.9$]. Except for marital status (OR 2.2; 95% CI 1.1-4.5), none of these associations were statistically significant on multivariable regression. Compared to those whose follow up data was not available, SIP data was available at follow up in older men (39.7 [12.7] vs. 43.6 [12.1]; $p = 0.06$), in those with higher AUDIT score (14.9 [2.2] vs. 15.0 [2.4]; $p = 0.8$), higher proportion of unemployed than employed [12 (70.6%) vs. 73 (59.4%); $p = 0.4$], significantly higher proportion of married than unmarried [76 (66.7%) vs. 12 (40.0%); $p = 0.01$], and in higher proportion of illiterate than literate [31 (64.6%) vs. 57 (59.4%); $p = 0.5$]. However, none of these associations were statistically significant on multivariable regression.

Table 9.8: Comparison of primary outcome (TLFB) completers and non-completers

Variable	Outcome completers n=92 (63.5%) Mean (SD) or n (%)	Outcome non completers n=53 (36.5%) Mean (SD) or n (%)	p value
Mean age	43.8 (12.0)	39.0 (12.7) mv=3	0.03
Marital status			0.008
Never married or post-marital	13 (43.3)	17 (56.7)	
Married	79 (69.3)	35 (30.7) mv=1	
Education			0.6
Literate	60 (62.5)	36 (37.5)	
Illiterate	32 (66.7)	16 (33.3) mv=1	
Occupation			0.2
Employed	76 (61.8)	47 (38.2)	
Unemployed	13 (76.5) mv=3	4 (23.5) mv=2	
Mean baseline AUDIT score	15.0 (2.4)	14.9 (2.2)	0.78
Treatment completion			<0.001
Dropped out of treatment	39 (50.0)	39 (50.0)	

Variable	Outcome completers n=92 (63.5%) Mean (SD) or n (%)	Outcome non completers n=53 (36.5%) Mean (SD) or n (%)	p value
Completed treatment	53 (79.1)	14 (20.9)	

9.3.6 Drinking and related outcomes (Tables 9.9a, 9.9b, and 9.9c)

a) *Alcohol consumed in past two weeks*: Although follow up data on TLFB were available in 92 participants, the baseline TLFB was available only for 78 (84.8%) participants. ~~After treatment with CAP there was~~ We observed a non-significant reduction in the mean alcohol consumed in past two weeks. In participants who completed treatment, baseline and follow up data were available in 44 participants. Baseline and follow up data were available in 34 participants who did not complete treatment. There was a non-significant reduction in drinking after completing treatment in participants who completed treatment and in those who dropped out of treatment. The SO accompanied 22 participants for at least one session. For participants in whom SO was present for at least one session the amount of drinking at follow up was significantly reduced compared to baseline. For participants in who SO was not present the reduction in amount drinking at follow up was not statistically significant.

b) *Abstinence*: Of the 92 participants for whom follow up data on TLFB were available, 41 (44.6%) were abstinent at 3 months post recruitment. At follow up, compared to those who did not complete treatment, a larger proportion of those who completed treatment were abstinent, although this was not significant (49.1% vs. 38.5%, $p=0.3$). At follow up, compared to those who were accompanied by a SO for at least one session, a larger proportion of those who were not accompanied by a SO for even one session were abstinent, but again, this was not significant (30.8% vs. 50.8%, $p=0.1$).

c) *Short Inventory of Problems (SIP)*: The baseline and follow up data for SIP were available in 47 participants. There was a significant reduction in the mean SIP score at follow up. In participants who completed treatment, baseline and follow up data were available in 32 participants. Baseline and follow up data were available in 15 participants who did not complete treatment. In participants that completed treatment there was a significant reduction in the SIP score at follow up. On the other hand, in participants who dropped out of treatment there was no significant reduction in the SIP score at follow up. For participants in who SO was present for at least one session ($n=14$) there was no significant reduction in the SIP score at follow up. For participants in who SO was not

present for any session (n=33) there was a significant reduction in the SIP score at follow up.

d) *Primary Health Questionnaire-9 (PHQ-9)*: Baseline and follow up data on PHQ-9 were available in 61 participants. There was a significant reduction in the mean PHQ-9 score at follow up. There was a significant reduction in the PHQ9 score at follow up in participants who completed treatment (n=38) but not in participants who dropped out of treatment (n=23). There was a significant reduction in the PHQ9 score at follow up in participants who were not accompanied by a SO for even one session (n=42) but not in those who were accompanied by a SO for at least one session (n=14).

Table 9.9a: ~~Effect of CAP on~~ Comparison of drinking and other outcomes before and after delivery of CAP

Outcome		Mean (95% CI)	p value
Alcohol (gms) consumed in past 2 weeks	(n=78)		0.1
	Pre-treatment	262.1 (199.0-470.6)	
	Post treatment	193.3 (112.9-273.7)	
SIP score	(n=47)		<0.001
	Pre-treatment	17.5 (14.5-20.5)	
	Post treatment	8.9 (6.0-11.7)	
PHQ-9 score	(n=61)		<0.01
	Pre-treatment	6.7 (5.3-8.1)	
	Post treatment	4.0 (2.8-5.2)	

Table 9.9b: ~~Effect of CAP on~~ Comparison of drinking and other outcomes before and after delivery of CAP in treatment completers

Outcome		Completed treatment		Dropped out of treatment	
		Mean (95% CI)	p value	Mean (95% CI)	p value
Alcohol (gms) consumed in past 2 weeks	Pre-treatment	324.5 (229.5-419.5)	0.2	181.5 (108.2- 254.8)	0.5
	Post treatment	233.9 (107.9-359.8)		140.8 (49.8-231.7)	
SIP score	Pre-treatment	19.9 (16.4-23.4)	<0.001	12.3 (7.0-17.7)	0.6
	Post treatment	8 (4.7-11.3)		10.7 (4.8-16.5)	
PHQ-9 score	Pre-treatment	6.3 (4.5-8.0)	0.001	7.4 (4.8-10.0)	0.13
	Post treatment	3.3 (1.8-4.8)		5.1 (3.0-7.3)	

Table 9.9c: ~~Effect of CAP on~~ Comparison of drinking and other outcomes before and after delivery of CAP in participants accompanied by SO

Outcome		Accompanied by SO		Not accompanied by SO	
		Mean (95% CI)	p value	Mean (95% CI)	p value
Alcohol (gms) consumed in past 2 weeks	Pre-treatment	298.3 (177.7-418.8)	0.02	244.3 (164.4-324.2)	0.8
	Post treatment	151.3 (69.8- 232.9)		225.1 (109.1-341.1)	
SIP score	Pre-treatment	19.9 (13.3-26.4)	0.1	16.5 (13.0-19.9)	0.0001
	Post treatment	13.2 (7.7-18.7)		7.0 (3.8-10.2)	
PHQ-9 score	Pre-treatment	6.7 (3.5-9.9)	0.3	6.2 (4.5-7.9)	<0.001
	Post treatment	5.4 (1.9-8.8)		3.0 (1.8-4.2)	

9.3.7 Predictors of abstinence

On univariate analyses none of the socio-demographic variables, treatment completion or presence of SO at treatment sessions predicted abstinence at follow up. However on multivariate analysis younger age predicted abstinence (Table 9.10).

9.3.8 Predictors of reduction of impact of drinking

Of the 47 participants for whom SIP scores were available for baseline and follow up, in 36 (76.6%) the SIP score had reduced between those two time-points. In the remainder it had remained the same or increased. On multivariate analyses treatment completion did not predict reduction in SIP scores at follow up (Table 9.11).

Of the 61 participants in whom PHQ9 data were available for baseline and follow up, the PHQ9 score had reduced in 38 (62.3%) participants and in the rest it had remained the same or increased. On multivariate analysis age and marital status did not predict reduction in PHQ9 scores (Table 9.12).

Table 9.10: Predictors of abstinence from alcohol

Variable	Non abstinent n=51 n (%)	Abstinent n=41 n (%)	Univariate Regression OR (95% CI)	p	Multivariate Regression OR (95% CI)*	p
Age						
≤40 years	19 (45.2)	23 (54.8)	1	0.07	1	0.04
>40 years	32 (64.0)	18 (36.0)	0.5 (0.2-1.1)		0.4 (0.2-0.9)	
Marital status						
Never married/Post-marital	8 (61.5)	5 (38.5)	1	0.6		
Married	43 (54.4)	36 (45.6)	1.3 (0.4-4.5)			
Educational status						
Literate	36 (60)	24 (40)	1	0.2		
Illiterate	15 (46.9)	17 (53.1)	1.7 (0.7-4.0)			
Employment status						
Employed	42 (55.3)	34 (44.7)	1	0.7		
Unemployed	8 (61.5)	5 (38.5)	0.8 (0.2-2.6)			
Treatment completion						
Dropped out	24 (61.5)	15 (38.5)	1	0.3		
Completed treatment	27 (50.9)	26 (49.1)	1.5 (0.7-3.6)			
SO present for one or more sessions						
No	30 (49.2)	31 (51.8)	1	0.08	1	0.08
Yes	18 (69.2)	8 (30.8)	0.4 (0.1-1.1)		0.4 (0.1-1.1)	

*Variables significant at p<0.1 on univariate analyses adjusted for each other and baseline AUDIT score

Table 9.11: Predictors of change in SIP score

Variable	Unchanged or increased n=11 n (%)	Decreased n=36 n (%)	Univariate Regression OR (95% CI)	p	Multivariate Regression OR (95% CI)*	p
Age						
≤40 years	2 (11.1)	16 (88.9)	1	0.1		
>40 years	9 (31.0)	33 (76.7)	0.3 (0.1-1.5)			
Marital status						
Never married/Post-marital	1 (16.7)	5 (83.3)	1	0.7		
Married	10 (24.4)	31 (75.6)	0.6 (0.1-6.0)			
Educational status						
Literate	7 (24.1)	22 (75.9)	1	0.9		
Illiterate	4 (22.2)	14 (77.8)	1.1 (0.3-4.5)			
Employment status						
Employed	10 (27.0)	27 (73.0)	1	0.3		
Unemployed	1 (11.1)	8 (88.9)	3.0 (0.3-26.8)			
Treatment completion						
Dropped out	6 (40.0)	9 (60.0)	1	0.07	1	0.08
Completed treatment	5 (15.6)	27 (84.4)	3.6 (0.9-14.7)		3.6 (0.9-14.8)	
SO present for one or more sessions						

Variable	Unchanged or increased n=11 n (%)	Decreased n=36 n (%)	Univariate Regression OR (95% CI)	p	Multivariate Regression OR (95% CI)*	p
No	7 (21.2)	26 (76.8)	1	0.6		
Yes	4 (28.6)	10 (71.4)	0.7 (0.2-2.8)			

* Variables significant at $p < 0.1$ on univariate analyses adjusted for baseline AUDIT score

Table 9.12: Predictors of change in PHQ 9 score

Variable	Unchanged or increased n=23 n (%)	Decreased n=38 n (%)	Univariate Regression OR (95% CI)	p	Multivariate Regression OR (95% CI)*	p
Age						0.2
≤40 years	8 (25.8)	23 (74.2)	1	0.06	1	
>40 years	15 (50.0)	15 (50.0)	0.3 (0.1-1.0)		0.5 (0.1-1.4)	
Marital status						0.06
Never married/Post-marital	0 (0)	6 (100.0)	1	0.05	1	
Married	23 (41.8)	32 (58.2)	0.4 (0.1-1.2)		0.3 (0.1-1.3)	
Educational status						
Literate	17 (39.5)	26 (60.5)	1	0.6		
Illiterate	6 (33.3)	12 (66.7)	1.3 (0.4-4.2)			
Employment status						
Employed	20 (39.2)	31 (60.8)	1	0.2		
Unemployed	1 (12.5)	7 (87.5)	4.5 (0.5- 39.5)			
Treatment completion						
Dropped out	11 (47.8)	12 (52.2)	1	0.2		
Completed treatment	12 (31.6)	26 (68.4)	2.0 (0.7-5.8)			
SO present for one or more sessions						

Variable	Unchanged or increased n=23 n (%)	Decreased n=38 n (%)	Univariate Regression OR (95% CI)	p	Multivariate Regression OR (95% CI)*	p
No	14 (33.3)	28 (66.7)	1	0.3		
Yes	7 (50.0)	7 (50.0)	0.5 (0.1-1.7)			

* Variables significant at p<0.1 on univariate analyses adjusted for each other and baseline AUDIT score

9.3.9. Acceptability and feasibility of delivering CAP

All the counsellors and supervisors involved in the case series were interviewed through FGDs and IDIs respectively. 18 study participants (9 treatment completers and 9 drop outs) and SOs were interviewed through IDIs. The mean age of the study participants was 42 years (SD 11.6), 5 (27.8%) were illiterate, 10 (55.6%) were employed, and 16 (88.9%) were married.

a) Counsellors' overall experience of counselling

Overall, all the counsellors gained confidence with the passage of time, enjoyed delivering CAP and reported their experience as "good". They reported receiving mixed responses from patients. Their relationship with some patients was getting stronger and they were even getting appreciation from patients' family members. *'Earlier I used to wonder if the counselling we do reaches the patient. Two of my patients stopped drinking completely. I got a call from their home that with the counselling treatment they had improved, and that they had not stopped drinking in the past despite taking treatment from the doctor for 12 to 13 years. The family members wanted to come and see what I had told him in the two to three sessions. One patient's wife even said that she would like to tell others about what we do here. When I heard this I felt happy and realised that the message that we are trying to deliver is getting across to the patients.'*

On the other hand some patients behaved with the counsellors in a rude or inappropriate manner, especially if they were drunk. Counsellors reported that successful completion of treatment worked as a motivator and that they felt good when the patient and/or his relatives appreciated the efforts made by the counsellor. The counsellors realised that they will not get good results with all patients and one counsellor said, *"...we have now learnt that everything will not be goody-goody. Sometimes we will get positive responses from patients and other times there will be not so good or negative responses. Now we have come to terms with that"*.

b) Challenges in the counselling process

Many patients and/or family members did not understand the counselling process and also demanded medicines for the treatment of their drinking problems. This also meant that some patients did not take the counselling intervention seriously. Furthermore, as they did not understand the counselling process they were not very serious about completing their homework tasks like completing the drink diary. Finally, consistent with experience from the case series with the therapists, there were some patients who came drunk for their counselling session. One counsellor describing problems with conducting sessions as patients were drunk said, *'Follow up with harmful drinkers is not as good as with depressed patients. And when I go for home visits, mostly either the patient is drunk or is sitting in a bar (local pub). So then it becomes very difficult. I visited the patient 2-3 times and each time when I visited, he was drunk'*. None of these findings required any adaptations to the manual as these had been encountered in the previous stage of the intervention development. Strategies for dealing with such situations were already described in the manual and only required appropriate implementation by the counsellors. This was emphasised to the counsellors during supervision.

c) Incompatibility of session based intervention with stages of change

As the case series progressed, it became increasingly clear that the patients who completed treatment required a maximum of four sessions. However, it was observed during supervision sessions while listening to session tapes that some patients moved faster through the intervention steps than others. Hence it was becoming increasingly impractical to define the intervention based on tasks to be achieved in a discrete session. For example, some patients entered treatment almost ready for change and the original session based structure of CAP dictated that even such a patient should get detailed assessment, personalised feedback, commitment to change and change plan before terminating the session. However dedicating a full session to these tasks designed to increase motivation was inappropriate and impractical for a patient who was already committed to change his drinking behaviour.

Adaptation: It was decided that, instead of dictating the goals that needed to be achieved in each of the four sessions, CAP would be a phasic intervention with goals being defined for each phase. Accordingly, CAP was divided into three

phases; the goal of Phase 1 was to help the patient understand their drinking and then helping them to decide on a change plan if they decided to do something about their drinking; the goal of Phase 2 was to help patients to acquire the necessary skills to make the change; and the goal of Phase 3 was to help the patients develop the skills to sustain the change once they made it. All patients did not go through all the phases and those who did, moved through them at a varying pace. For example, a patient who had never thought about his drinking and did not want to make any change to his drinking would go through Phase 1 (assessment and feedback) and then be discharged. On the other hand a patient like the one described in the example above (i.e. entering treatment almost ready for change) could rapidly complete Phase 1 and progress to Phase 2 (learning skills to implement the change plan) in session 1 itself.

d) Controlled drinking as treatment goal

Harmful drinking encompasses patients with a wide range of severity of drinking problems and treatment goals need to be tailored to individual needs, with flexibility in delivery of the intervention to accommodate this diversity. Many patients, especially those at the lower end of the AUDIT cut-off score for harmful drinking, expressed the desire to choose controlled drinking as a drinking goal. Ignoring the patient's stated goal to promote abstinence increased the risk of treatment drop out. Furthermore, for harmful drinkers controlled drinking was a perfectly reasonable goal. This issue had also been encountered in the case series with therapists and the case series with the lay counsellors allowed further exploration. Considering the advantages of controlled drinking as a treatment goal (outlined in Table 8.9) and the expressed desire of patients to control their drinking (rather than abstaining) it was decided that it should be added as a treatment goal in the manual.

Adaptation: In the CAP manual, controlled drinking was emphasised as a potential drinking goal as much as abstinence was. CAP emphasises that the drinking goal should remain the patient's decision, but that this decision should be made after the counsellor has provided the patient with adequate information to enable him to make that decision, e.g. on the type of patients for whom controlled drinking might be contraindicated. Furthermore, detailed information

has been provided in the manual on how to empower patients choosing the controlled drinking goal to achieve the goal using appropriate strategies (Extract from the manual below).

'This is a challenging situation for us. On the one hand, we have a responsibility to inform our patients if they want to try something that might be detrimental to their health. Yet, on the other hand, we also need to maintain our collaborative way of working with the patient in which they choose the goal they want to work towards. The following statements can help you to frame your response to such a situation: *You are saying that you want to control your drinking (or to 'cut down'). Earlier, you had also told me that you have diabetes. What you decide to do is very much your decision, but I do want to tell you that there are real risks to you – to your physical health – if you do decide to continue drinking, even if you drink in a much more controlled fashion. And so even though this is very much your decision, I do want you to know that stopping drinking completely would be a safer choice for you. If you don't drink then you can be sure that you won't get any problems due to your drinking. However, whatever you decide, I will help you to achieve that goal*'.

e) Practical barriers to attending CAP sessions at the PHC and telephone delivery of CAP

Drop-out rates were high and the common reasons were practical barriers such as lack of time to attend counselling because of work commitments and inability to travel to the PHC for financial reasons. This was a problem that was encountered in the previous step of intervention development too and it was decided to test intervention delivery at home or using the telephone. Using the telephone to deliver sessions to enhance treatment engagement came with its own set of challenges e.g. the patient not having a phone of his own and providing a family member's number, poor network connectivity, lack of comfort for the counsellor and patient.

On the other hand, home delivery of CAP was relatively better received. One counsellor describing the challenges of doing telephone counselling said '*Once, while doing telephone counselling we got disconnected in the middle of a session. The patient then messaged me to ask for my personal number. When I called him again I could hear his friends talking in the background. When I*

would ask him whether he understood what I was telling him he would say yes but I would get the feeling that he was making fun of me and sometimes I used to feel that the person talking at the other end was not the patient, but his friend’.

Adaptation: In the initial manual, after the first intervention session in the PHC patients were given the choice of follow up sessions at the PHC or home or via telephone. Considering the logistical difficulties as well as the separate set of skills required for telephone delivery of therapy, it was decided to drop this latter option. Patients were still given the choice of further sessions taking place in either the PHC or at home.

f) Challenges to home visits

Besides practical problems like getting to difficult-to-reach villages and difficulty in locating patient’s addresses in some areas, one of the biggest problems that the counsellors faced during home visits was the lack of privacy while delivering CAP. Family members and sometimes neighbours would come and sit around while the session was being conducted at home. Besides depriving the patient of privacy this was a distraction, as they would often make unhelpful comments. One counsellor described it as follows: *‘If we are conducting a session at the patient’s home such things happen. Someone (family member or neighbour) interrupts us, or someone makes a comment. The patient is not comfortable with us, while talking with us he is doing some other thing, and his attention is not on the session. When someone interrupts we request the patient to tell him or her to leave. However it is difficult to do that. The neighbours are very inquisitive and want to know details of what we are doing and why we are doing it’.* Finally, some of the patients were drunk when the counsellors arrived for the session and this interfered with the delivery of the session and sometimes made the counsellors feel unsafe. This did not require any changes to the content of the manual. However, brainstorming was done with the counsellors to find out ways in which these difficulties could be overcome. One of the solutions was to deliver CAP at other places that were mutually convenient for the counsellor and the patient e.g. local village temple.

g) Involvement of family in intervention

Although CAP emphasised family involvement, family members sometimes saw counselling as a waste of time. Some family members were tired of the patient's drinking habit and believed that nothing could be done to help them. They also questioned how a talking treatment could help when medications could not. There were also some family members who made unhelpful comments about the patients. *'One patient's wife said that she has been trying to improve her husband for so many years, but in vain. She said that she did not understand what I could do to change him. She said she would send the patient for the counselling session but keeps grumbling. Sometimes she comes to the PHC, tells me that I am wasting my time, that he (patient) is not going to improve, and that he does not listen to anybody not even his children'.* Another counsellor had a similar experience during a home visit, *'He (patient) was drunk. I told him that I have come from the PHC and his daughter directly started saying that we shouldn't waste our time on him and instead use that time to help someone else. She said that her father would not improve and that he couldn't be trusted'.* Finally, many patients were also unwilling to involve a family member, as they did not want to disclose to them the true extent of their drinking problems.

Adaptation: It was decided to try to involve a SO in at least one session, preferably the first, to get a more rounded picture of the problem. Subsequently if the SO was found to be helpful then the decision about further involvement of the SO would be made on a case-by-case basis at the discretion of the counsellor and the patient.

h) Treatment of dependent drinkers

Although CAP was designed for men with harmful drinking, it was seen that a third of the patients with an AUDIT score of 12 and above had alcohol dependence.

Adaptation: In the study settings i.e. primary care, patients with alcohol dependence do not normally receive any intervention: at best, if the dependence is identified, it might be suggested to the person that they visit the local de-addiction or detoxification in-patient facility and ask for treatment there. Within the PHC they do not normally otherwise receive any physical or psychosocial intervention. In the initial stages of the case series, patients with

alcohol dependence were referred only to the de-addiction centre. This was later changed as it was agreed that refusing CAP to this group of patients with the most severe form of AUD (dependent drinkers) while delivering it to the group with relatively less severe AUD (harmful drinkers) would have been untenable for the credibility of the programme; and also would have been unethical, given the fact that there was good evidence to suggest that psychosocial intervention is an important component of overall treatment for dependent drinkers. Hence CAP was modified to also address the needs of men with alcohol dependence. Two major changes were made to accommodate this expansion of the patient group: a) a structured referral pathway was built into the manual so that patients with alcohol dependence also received referral for medically assisted detoxification to the local detoxification centre to supplement CAP, and b) information about medications for alcohol dependence was provided in the manual so that the counsellors could provide appropriate psychoeducation to the patients. Other than that, patients with alcohol dependence received exactly the same psychosocial intervention as the patients with harmful drinking^{†††}.

i) Differential skills acquisition by counsellors

The supervisors reported that there were differential rates of acquisition of therapy skills amongst the counsellors, with some acquiring skills at a faster rate as compared to others. Counsellors who had good generic counselling skills (e.g. open ended questioning, reflection) were performing better than the counsellors who didn't. On the other hand, counsellors who had good generic counselling skills were also getting by using those skills without refining their CAP specific skills (e.g. rolling with resistance).

Solution: Refresher trainings were conducted for the counsellors at regular intervals. Furthermore, during weekly supervision, along with group supervision in the morning, skill-building sessions were built into the supervision day in the afternoon. In these sessions the counsellors would discuss and practice various CAP specific skills through demonstration by supervisors followed by role-plays.

^{†††} 86 participants with alcohol dependence (AUDIT 20-40) entered this case series but these are not included in the analyses presented in this chapter.

j) Structure and content of supervision

The supervisors reported that supervision in a large group had its disadvantages as every counsellor did not get a chance to contribute and fewer cases could be discussed. Furthermore, it was felt that along with qualitative feedback given during supervision sessions the counsellors should also receive feedback about their performance using the quantitative scores generated using the Q-CAP.

Solution: It was decided that the supervision would be conducted in smaller groups allowing for all the counsellors to make a contribution to the discussion. It was also decided that the counsellors would be provided feedback about their performance based on their mean Q-CAP domain scores at the end of every quarter.

9.4 Output

At the end of this case series the primary output was the final version of the CAP intervention that was then delivered in the pilot RCT described in the next chapter. The final version of the CAP intervention was informed by the findings in the case series and the details of the adaptations to make the intervention contextually appropriate are described in the 'Results' section of this chapter. A brief summary of the contextual adaptations made to the intervention is as follows. One of the major adaptations was to convert the intervention from a session based one into a phasic intervention. This made the intervention more flexible and allowed the counsellors to be more nimble-footed in individualised matching of the goals of the sessions to the needs of the patients. Although the starting point of the intervention development process was an abstinence-focused intervention, CAP gradually evolved into an intervention, which gave the harmful drinker the choice of abstinence or controlled drinking as treatment goals. The intervention delivery was changed from being predominantly PHC based to delivery in the community if that was more convenient for the patient. The intervention also went from taking a stance that SOs should be assertively recruited in the intervention process to a more pragmatic approach of recruiting SOs only if they aided the therapeutic process.

In patients with AUD, one of the complexities arises from the considerable heterogeneity both between and within the categories of hazardous, harmful and dependent drinkers, all of which are clumped together under the AUD umbrella. Furthermore, even an intervention designed for harmful drinkers is unlikely to have a “one size fits all” solution. In such a scenario, having an intervention that has a fixed session based structure is not fit for purpose and hence a phasic intervention allows a level of flexibility that makes specific intervention strategies available based on the extent of readiness of change and other requirements specific to individual patients. In developing a flexible intervention the goal was also to create an intervention that more closely resembles what a clinician would do in the real world, away from the more sanitised world of clinical research. This was done with one eye on the eventual scalability of CAP by making it more attractive to clinicians who are reported to believe that rigidly prescriptive interventions interfere with clinical judgment, therapeutic alliance, and fail to address the complexities of clinical work (Moras, 2002).

Moral and disease models have dominated the narrative about the treatment of AUDs since the early 1930s (Jellinek, 1960). These models considered abstinence as the only alternative to AUD and individuals who had drinking problems were seen as either immoral or diseased. The counterpoint to this narrative is the harm reduction perspective, a pragmatic approach that aims to reduce the harmful consequences of heavy drinking and incorporates drinking goals that can be matched to the clinical condition and needs of the individual. Since the pioneering research of the Sobells (Sobell and Sobell, 1973; Sobell and Sobell, 1976) demonstrated that controlled drinking could be a viable treatment option in AUD there have been several studies reinforcing the findings in clinical samples (Foy et al., 1984; Sanchez-Craig et al., 1984) as well as in untreated AUD where controlled drinking was seen as a path to eventual recovery (Sobell et al., 2000). For CAP, having controlled drinking as a drinking goal was in response to the observations in the case series. In a scaled up programme implementing CAP, having controlled drinking as a drinking goal would have the additional benefit of reducing a specific barrier to access. It has been proposed that one of the barriers of access to treatment for AUD is the public knowledge about the abstinence model promoted by most programmes

(Miller et al., 1992). A programme with an intervention like CAP which also offers controlled drinking as a drinking goal has the potential to attract and retain individuals who want to reduce the risks associated with heavy drinking, without completely quitting.

The survey of international leaders in psychiatry from almost 60 countries (two third of which were LMIC) which informed the World Psychiatry Association 2008–11 Action Plan clearly emphasised task sharing in primary care to maximise coverage, and increase access to psychosocial therapies in low resource settings (Patel, 2009; Patel et al., 2010). However, this could be only the first step in increasing access to mental health care as there is evidence to suggest that logistical barriers like lack of money, transportation, and childcare support play a big role in reducing access, sometimes more than traditional barriers like stigma (Alvidrez and Azocar, 1999; Kopelman et al., 2008; White, 1986). Home-based delivery, web based interventions and telephone delivery are a few strategies to overcome such logistical barriers. Web based delivery of CAP was never considered in PREMIUM as the penetration and coverage of the Internet in India is not optimal. Telephone delivery of interventions comes with several potential advantages like increased access to psychosocial interventions and reduced resource intensity (Depp et al., 2010). The flip side of this delivery method are limitations related to diminished therapeutic alliance, added cost of development, training, devices, and implementation, and concerns about privacy/confidentiality and safety (Depp et al., 2010; Haas et al., 1996). We tested telephone delivery and home-based delivery of CAP and dropped the former because of a range of difficulties faced by the counsellors as well as the fact that the study was not optimally designed to test the feasibility of this approach. Eventually, it was decided that home-based delivery of CAP would be offered as an alternative to clinic-based delivery in the PHC/CHC. This also threw up other challenges as described in this chapter but they were minimised with further training and extending the definition of ‘home-based’ to any venue which was safe and mutually convenient for the patient and counsellor.

An important component of the CAP intervention is SO involvement. Since AUDs affect other members of the family in a negative way (Orford et al., 2013), including a SO in therapy could assist in several ways, such as reducing

problems in the family which might be contributing to the drinking, teaching techniques for improving communication and planning alternative positive activities to replace drinking. The rationale behind involving SOs in psychosocial interventions for AUD is that family relationships are intimately and reciprocally related to the problem drinking. AUD impairs relationship functioning and the partner's attempts to control or manage the excessive consumption can prompt craving, reinforce the behaviour or trigger relapse (Powers et al., 2008). Usually SO involvement in the therapeutic process is through trying to encourage a reluctant patient into treatment, the joint involvement of the SO and the patient in treatment, or through treatment which is directed solely at the SO to alleviate the impact that the family member's drinking has on the SO (Velleman, 2006). SO involvement in CAP evolved from being a joint involvement of the patient and SO to a more flexible approach where the extent of the SO involvement was determined by the level of interest and engagement demonstrated by the SO. This was informed by the experiences in the case series where involvement of SOs was sometimes seen to be counter-productive to the therapeutic process

Finally, another major adaptation to the CAP manual was in relation to the target population for the intervention i.e. inclusion of dependent drinkers. As described above, several reasons prompted this decision, not least the principles of equity and justice. Although the intervention was not designed with this target population in mind, as evidenced by the focus of the preceding treatment development steps on harmful drinking, there was no reason to believe that at least some of the strategies would not be helpful for dependent drinkers. Although this could not be definitively tested in the pilot RCT (described in Chapter 10) or the on-going definitive RCT, we would be able to get some preliminary data on impact which could then be used to inform future intervention development studies.

A summary of the quantitative assessments is as follows. There were high treatment drop-out rates, but on an average patients received two sessions, an optimal dose as conceptualised when developing the intervention. There was a good convergence between the quality assessments of therapy done by the experts and the lay counsellors. Although there was no ~~the CAP intervention did not lead to a significant reduction in the drinking~~ there was ~~it led to a significant~~

improvement in the impact of drinking as measured using the SIP and the PHQ 9. In participants that completed treatment there was a statistically significant reduction in the SIP and PHQ 9 scores at follow up. This was not the case with those who dropped out of treatment. There were inconsistent results with regards to SO involvement and treatment completion. For participants in whom SO was present for at least one session the amount of drinking at follow up was significantly reduced compared to baseline. For participants in whom SO was not present for any session there was a significant reduction in the SIP and PHQ9 scores at follow up. The only socio-demographic predictor of drinking outcome (abstinence) was younger age.

Drop-out rates from psychosocial treatments are generally high, especially so for alcohol use disorders. In the case of PREMIUM the opportunistic screening meant that most of the patients who were recruited in the case series were attending the PHC for physical health problems (sometimes related to their heavy drinking) and had never considered their drinking as problematic. Engaging and retaining such patients into a treatment for harmful drinking was particularly challenging and could be one of the reasons for the high drop-out rates. It is also a possibility that for such patients, 1-2 sessions were optimal treatment and there was no requirement for more sessions. Nonetheless, in a bid to reduce the drop-out rates, strategies like sending the patients a reminder SMS a day before the therapy session were implemented in the next step of the intervention development process.

It was encouraging to find that there were no significant differences in the quality ratings given by the intervention experts and the lay counsellors. This has particular implications for the eventual scaling up of the CAP intervention if it is cost effective. An important component of an intervention programme is consistent supervision that is required to sustain the quality of the intervention delivered. However in resource poor settings in LMICs it would be impossible to have a clinical supervision system that is dependent on experts leading it. Our findings suggest that well-trained lay counsellors are able to provide supervision that is at least quantitatively as good as that provided by experts; and this is an imminently scalable model.

Finally, the outcome results give evidence of impact of the CAP intervention, especially in terms of improvement in the psychosocial domains. With regard to measuring impact of the CAP intervention, the aim of this study was to measure changes in drinking and its psychosocial impact. We used objective measures of these outcomes and it is possible that these do not map on perfectly to subjective expectations of the treatment. So, a patient might have significantly reduced his drinking (a positive objective impact) but might not have achieved his chosen goal of 'abstinence' (a negative subjective impact). However, it is not possible to tease out such finer details as the study was not designed to triangulate patients' treatment goals with measured outcomes. The findings with regards to potential predictors of impact are inconsistent and vary based on the outcome measured. It would be too hasty to read too much into the impact or the predictors of the impact as this case series was not powered and designed to give definitive evidence about any of these outcomes. The advantage of our study design (treatment cohort) is that it establishes the temporal relationship between the exposure (the CAP treatment) and the various outcomes measured. On the other hand confounding remains a possible threat to validity and unmeasured factors that motivated the decision to accept the CAP treatment (e.g. the physical health problem that initiated PHC contact) could be predictive of changes in outcomes. Several factors besides CAP could have contributed to the change in drinking and other outcomes. These include factors external to therapy (e.g. incidental positive changes in the patient's life, the emergence of social support), natural recovery, and placebo effect i.e. the patient's belief and trust in the principles of CAP. Finally, change could have occurred due to 'common factors' (factors that are characteristic of psychotherapy in general e.g. empathy, warmth) and not due to specific CAP components. Hence this study does not allow us to make a definitive conclusion on the 'effectiveness' of the CAP intervention; and indeed that was not the intended goal of the study. However, we need to treat these results as preliminary evidence of 'impact' worthy of further exploration.

At the end of this step of the intervention development process, the selection of the final set of lay counsellors was done based on triangulating data from various sources as follows: a) The scores on Q-CAP during the course of the case series; b) Scores on standardised role plays designed specifically to test

competency (Appendices 20 to 22); c) Rating by the therapists (supervisors) on perceived global competency on a Likert scale of 1 (Poor) to 5 (Excellent) (Appendix 23); and d) Rating by the therapists (supervisors) on 'attitude towards work' on a Likert scale of 1 (Poor) to 5 (Excellent) (Appendix 23). A mean score was generated from the scores from these various sources and the lay counsellors were ranked in a descending order based on that score. The top twelve lay counsellors were then selected for the pilot RCT described in Chapter 10.

The other output of this step of the intervention development process was the final CAP intervention that is briefly described as follows. CAP has a core of Motivational Interviewing around which the various strategies are delivered. These strategies include detailed assessment and personalised feedback, handling drinking urges, dealing with difficult emotions, handling peer pressure, problem solving; and then working to prevent or manage lapse and relapse. CAP is delivered in four sessions over three phases. In the 'Initial Phase' the counsellor helps the patient understand the problems his drinking is causing and raises the issue that he may need to change. This is done through a sequential process of a) detailed assessment of the drinking patterns and its impact on the various domains of the patient's life; b) personalised feedback about his drinking pattern, how and why his drinking may be harmful, and how it may be related to any problems or issues that he faces; c) facilitation of a commitment to change from the patient; and d) generation of a change and action plan to summarise what the patient wants to do to change his drinking and its related problems, and the actual actions that the patient will take to achieve this goal. In the 'Middle Phase' the counsellor helps the patient to develop thinking and behavioural skills and techniques, namely drink refusal, handling the urge to drink, problem solving and handling difficult emotions, which would allow the patient to make the changes that he desires. In the 'Ending Phase' the patient learns how to manage potential or actual lapses and relapses using these thinking and behavioural skills and techniques. The first session will be delivered in the PHC/CHC after the randomisation and subsequent sessions will be delivered in the PHC/CHC, the patient's home or in any other safe place which is mutually convenient for the patient and the lay counsellor. An attempt will always be made to engage a SO into the treatment,

especially to facilitate assessment and development of the change plan. The SO's involvement in subsequent sessions will be encouraged based on how useful it is perceived to be by the patient and the lay counsellor.

To summarise, at the end of this step of the intervention development process we had preliminary evidence of the potentially favourable impact of the CAP intervention, and potential predictors of that positive impact. Furthermore through the evidence generated from the qualitative component of the study we were able to make contextual adaptations to the content/structure (e.g. phasic delivery of the intervention) as well as the delivery (e.g. follow up sessions at home). Finally, the triangulation of the quantitative and qualitative findings (e.g. the unhelpfulness of SO involvement at times and the poorer impact on some outcomes if SO was involved) also informed the adaptation of the manual. So, at the end of this step of the intervention development process, we had a final manual and a set of trained lay counsellors ready to deliver the CAP intervention in a pilot RCT, which would enable us to fine tune procedures for the definitive RCT and to generate preliminary evidence of effectiveness of the CAP intervention.

Chapter 10: Pilot study- Preparing for the Definitive Randomised Controlled Trial^{†††}

10.1 Background

In the previous chapter we described the case series in which the lay counsellors delivered the CAP intervention. During the case series the CAP manual was iteratively refined and at the end of that step of the intervention development process we had a final intervention manual for CAP, a psychosocial intervention for harmful drinkers to be delivered by lay counsellors in primary health care settings (Figure 10.1).

The MRC framework (Craig et al., 2008) recommends that before evaluating a complex intervention, piloting should be done to be confident that the intervention can be delivered as intended, that safe assumptions about effect sizes and variability can be made, and preliminary estimates of recruitment and retention rates can be made.

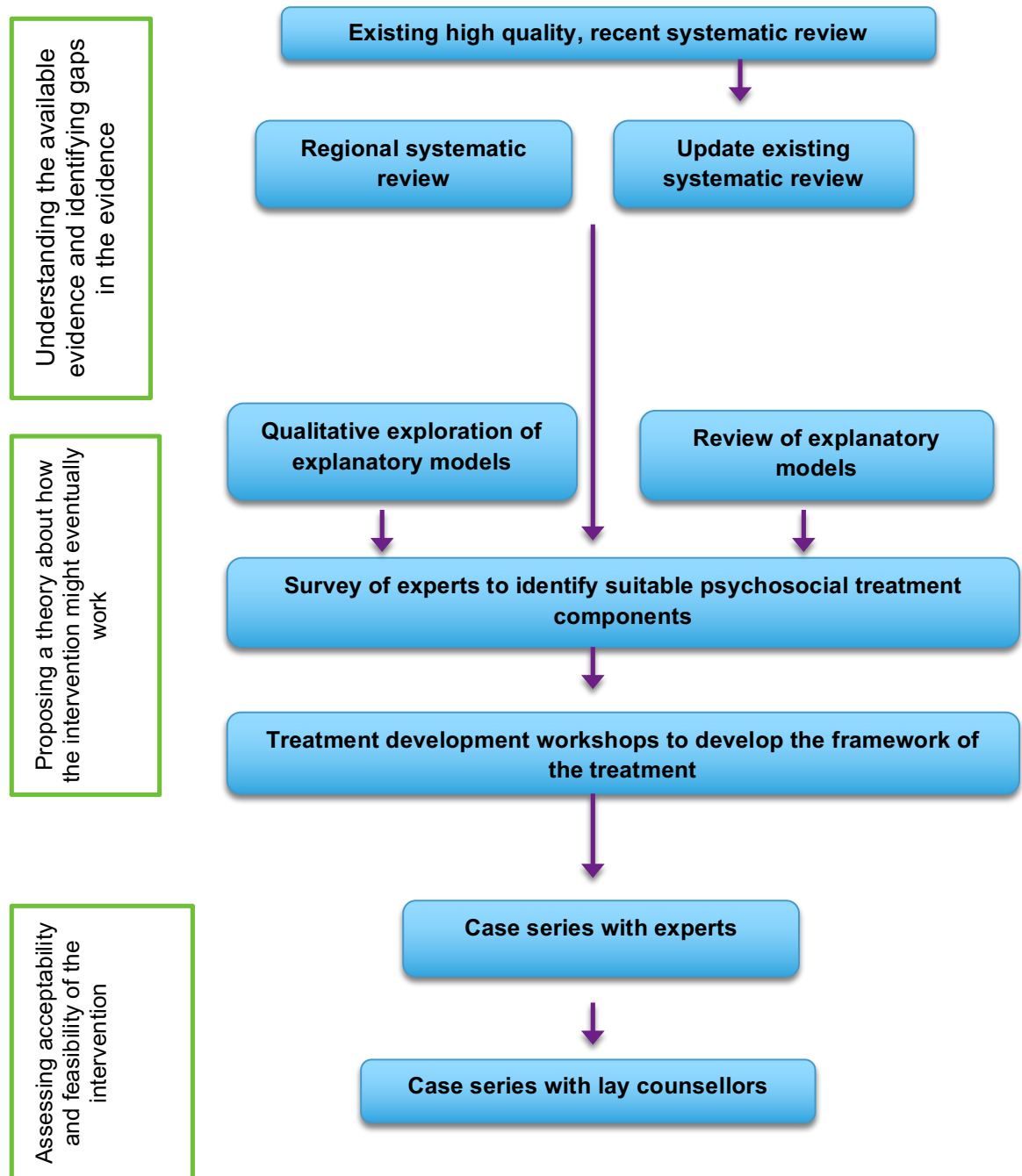
Accordingly a pilot study was conducted to

- 1) Evaluate the preliminary effectiveness of CAP compared to enhanced usual care (EUC);
- 2) Generate preliminary information for the definitive randomised controlled trial (RCT) to evaluate the cost effectiveness of CAP e.g. estimate the likely rates of recruitment and dropouts; and
- 3) Fine-tune the procedures for the eventual definitive RCT e.g. randomisation procedures.

The hypotheses were that the CAP intervention would be superior to EUC in 1) reducing alcohol consumption; and 2) reducing the physical, psychological, social, intrapersonal, impulsive, and interpersonal consequences of drinking, in men with harmful drinking at 3 months after recruitment.

^{†††}Author contribution to the methods: I contributed to the development of the study design, contributed to the development of data collection tools, contributed to the supervision of the counsellors, analysed the data, synthesised the results, and interpreted the findings.

Figure 10.1: Progress of the intervention development process



10.2 Methods

10.2.1 Setting

The study was conducted in eight clinics in the North district of Goa. The case series described in Chapter 9 was conducted in three Community Health Centres (CHCs) (Pernem, Valpoi and Ponda) and eight Primary Health Centres (PHCs) (Sanguem, Loutolim, Siolim, Candolim, Bicholim, Sanquelim, Cansarvanem, and Aldona in Goa. During the course of the case series it emerged that the PHCs and CHCs in the South Goa district had psychiatrists deputed under the District Mental Health Programme (DMHP) and he/she

visited the PHC/CHC once a month. To avoid contamination of the CAP intervention and the control arm by the intervention delivered by the DMHP psychiatrist, it was decided to conduct the pilot RCT only in the PHCs/CHCs in North Goa where the DMHP was not functional. Hence the pilot RCT was conducted in two CHCs (Pernem and Valpoi) and six PHCs (Siolim, Candolim, Bicholim, Sanquelim, Cansarvanem, and Aldona) in Goa.

10.2.2 Study design

A parallel arm double blind individually randomised controlled trial design comparing CAP with EUC.

10.2.3 Sample

a) Inclusion Criteria

The following patients were eligible for participation in the pilot RCT:

1. Male patients with harmful drinking or dependent drinking (Alcohol Use Disorders Identification Test [AUDIT] score of 12 and above). Dependent drinkers were also included as the plan was to recruit harmful and dependent drinkers in the definitive RCT; and
2. Age between 18 years and 65 years. Patients below the age of 18 years were excluded, as participants under this age require parental consent for participation in research. Patients above the age of 65 years were excluded as less than 1.5% of men with AUD were above 65 years, as confirmed in the case series.

b) Exclusion criteria

The following patients were ineligible for participation in the study:

1. Required emergency medical treatment and/or in-patient admission;
2. Was having an acute exacerbation of a severe mental disorder at the time of screening e.g. active hallucinations;
3. Were unable to communicate clearly due to a speech or hearing disability;

4. Did not comprehend any of the programme's four languages (Konkani, Hindi, Marathi or English);
5. Was already receiving treatment for AUD from a psychiatrist;
6. Could not confirm that they would be staying in the same residence for the duration of the study (6 months) to enable completion of therapy and assessment of outcomes;
7. Did not reside in the catchment area.

The first four exclusion criteria excluded participants who would not be able to participate in a counselling intervention for reasons related to communication. The fifth criterion was to avoid contamination of the CAP intervention by any other intervention being delivered by the psychiatrist. The remaining exclusion criteria excluded participants who were potential drop-outs from treatment and/or outcome evaluation because of their itinerant circumstances.

Pilot studies do not provide a meaningful effect size estimate for planning subsequent studies due to the imprecision inherent in data from small samples (Leon et al., 2011). However, they inform feasibility and identify modifications needed in the design of a subsequent larger, hypothesis testing study (Leon et al., 2011). This pilot study too was primarily conducted to evaluate the feasibility of recruitment, randomization, retention, and assessment procedures; and not for hypothesis testing. Its main function was to enhance the probability of success of the subsequent planned definitive RCT. Hence, rather than being based on formal sample size calculations the sample for this pilot RCT was based on the pragmatics of recruitment and the requirements for examining feasibility. Several studies have made recommendations on how to decide the sample size for a pilot study. It is generally suggested by different sources that the sample size should be a) 10% of the projected sample size for the definitive study that will be informed by the pilot study (Connelly, 2008; Treece and Treece, 1982) or b) 10-40 participants in each group (Billingham et al, 2013; Hill, 1998; Julious, 2005). This pilot study fulfilled both these criteria as the sample was 53 and that was more than 10% of the sample size calculated for the definitive RCT (n=400).

10.2.4 Screening and informed consent

Consecutive eligible PHC/CHC attendees were screened for harmful drinking. Screening was conducted by trained health assistants using the AUDIT (details provided in Chapter 9), prior to their consultation with the PHC/CHC doctor. Patients who screened positive for harmful drinking or dependent drinking (scoring 12 or above on the AUDIT) were invited to participate in the pilot RCT by the health assistant after their consultation with the PHC/CHC doctor. After providing the eligible patient with written and verbal information about the study, consent for participation was sought. For eligible patients who refused consent to participate, the following minimum data was collected: age, education, marital status, and employment status.

10.2.5 Baseline assessments

Data on the baseline alcohol use disorder status was already available from the screening with AUDIT. The health assistant also collected the following socio-demographic data: age, marital status, employment status, and educational status.

The decision to limit baseline assessments to only the AUDIT (and not the other outcome tools) was because it is theorized that the detailed assessment of drinking behaviours and their impact on a person's life by itself contributes to the positive effects of interventions for AUD and thus leads to a reduction in drinking outcomes in both the intervention and control groups, and a failure to find differences between different interventions tested in the same RCT e.g. Project MATCH (Clifford and Maisto, 2000; Project MATCH Research Group., 1998; WHO Brief Intervention Study Group, 1996; Ogborne and Annis, 1988; Sobell et al., 1987). The process of reporting one's own drinking during assessment forces the drinker to reflect on his own behaviour and this in turn could initiate self-monitoring, which allows the drinker to recognise discrepancies between current drinking and personal values, leading to change in drinking behaviour. In accordance with such findings, a detailed baseline assessment of drinking was not done in this pilot RCT.

10.2.6 Randomisation

The randomisation was conducted after the baseline assessments. A statistician based at the London School of Hygiene and Tropical Medicine

(LSHTM), and independent of the pilot RCT, generated the randomisation list. The randomisation list was stratified by PHC in randomly sized blocks of two to four participants. To maximise allocation concealment the randomisation code was concealed using sequentially numbered opaque sealed envelopes (Schulz and Grimes, 2002). The randomisation envelopes were prepared at LSHTM by personnel independent of the pilot RCT and then shipped to the study site. The envelopes were taped down for extra security. To prevent the allocation code from being visible through the envelope, the envelope contained a piece of card paper folded in two, and inside this folded card paper was placed a sticker with the trial ID number and allocation. The data manager performed a daily check to examine if allocations done were consistent with the allocation code.

10.2.7 Intervention

The CAP intervention delivered in the pilot RCT was the final version that was an outcome of the refinement in the case series with lay counsellors and has been described in section 9.4 of the previous chapter.

10.2.8 Enhanced usual care

The control arm in the pilot RCT received enhanced usual care (EUC). In India, usual care for harmful drinking in primary care is no care at all as most cases with harmful drinking are not identified and, even those who are sometimes identified, do not receive any psychosocial intervention, which is the primary intervention modality for harmful drinking. For this pilot RCT, EUC included providing the primary care physician with a) a contextualized version of the mhGAP guidelines (WHO, 2010b) for management of AUD; and b) the screening results (interpretation of the AUDIT score) of each screened patient.

The contextualized version of the mhGAP guidelines provided details on what a primary care physician could do to help a person with AUD. To summarise, it gives information about the following: a) Taking a detailed alcohol use history through open ended questioning. This includes the onset and progression of drinking, current patterns of drinking and impact of drinking on various domains of the patient's life; b) Physical examination of the patient for evidence of long-term heavy alcohol consumption e.g. liver disease; c) Blood investigations that should be considered; d) Providing examples of ways that the harmful use of

alcohol can be reduced e.g. not going to pubs or other locations where people use alcohol; e) Talking with the patient about the reasons he uses alcohol e.g. a balanced discussion about the perceived benefits of drinking and the actual and/or potential harms; and f) Advising patients to join existing self help groups like Alcoholics Anonymous (AA).

10.2.9 Interventionists

The lay counsellors for the pilot RCT were selected from the pool of lay counsellors (n=19) who delivered CAP during the case series and the selection process is described in section 9.4 of the previous Chapter. Of the 12 lay counsellors selected for the pilot RCT, one each was placed at the eight PHCs/CHCs and four as back up to cover for counsellor attrition. While the top eight counsellors provided CAP at the PHCs/CHCs, the back up counsellors provided CAP at the local detoxification centre. The back up counsellors were placed in the detoxification centre to provide CAP so that their skills could be kept updated and they could move in immediately to cover for counsellor attrition, if any.

10.2.10 Supervision

Group supervision of the counsellors evolved from the therapist led format (in the case series) to a peer group format led by peer counsellors. The supervision groups were conducted once a week in the field office. Group supervision involved the following a) Selected audio recordings of therapy sessions were assessed in a peer group for quality using the Q-CAP and accompanied by feedback provided by the peers. The group supervision was led by one of the counsellors in rotation. A therapist would sit in on the group supervision sessions as an observer and also independently rate the session on Q-CAP. At the end of the group session, the therapist would provide his/her feedback on the overall session. He/she would do this only after the peers had rated the session on Q-CAP to avoid contamination of the peers' ratings by the therapist's feedback; and b) In a separate joint session with all the counsellors any difficult cases were discussed and any skills/techniques/ strategies which the counsellors found difficult to deliver were practiced in role plays after demonstration by therapists. Singla et al (2014) have described and evaluated this method of peer supervision adopted in PREMIUM.

Group supervision of the counsellors was supplemented by individual face-to-face supervision conducted twice a month at the PHC/CHC by a therapist. During individual supervision the therapist reviewed the case load of the counsellor while focusing on a) progress of individual patients on the counsellor's caseload; b) quality of documentation maintained by the counsellor e.g. session notes; and c) addressing any PHC/CHC or counsellor-specific practical difficulties e.g. difficulties in engaging with staff at the PHC/CHC or difficulties in conducting home visits.

10.2.11 Data

The following data were collected:

a) Outcome data: Outcome data was collected at three months post-recruitment. The outcome measures were the Time Line Follow Back (TLFB), the Short Inventory of Problems (SIP) and the AUDIT. All these measures have been described in detail in Chapter 9. Although the AUDIT was designed as a screening tool and hence might not have all the characteristics of a complete outcome tool, in recent times it (or its variants) is being increasingly used as an outcome measure in RCTs (Kaner et al., 2013; Wallace et al., 2011). All baseline and follow up outcome assessments were audio-taped (with patients' consent), and the outcome team supervisor reviewed randomly selected tapes for quality assurance (Schulz and Grimes, 2002). One of the critiques of multiple hypotheses testing as we have done is the possibility of getting a positive finding by chance. Furthermore, the results become difficult to interpret if there are inconsistent findings from different tools that measure similar constructs e.g. AUDIT and TLFB. However, we used multiple tools and tested several hypotheses as one of the goals of a pilot RCT is to allow for identification of appropriate tools and fine tune hypotheses for the definitive RCT.

To minimise the risk of unmasking the following procedures were followed: i) The outcome assessments were carried out by an independent team of field workers who had no contact with the PHC/CHCs and conducted assessments at the patients' homes or any other convenient place; and ii) The intervention

team and outcome evaluation team were based in two different physical locations.

b) Process indicators: Process indicators were also collected to describe the recruitment procedures and intervention delivery as follows:

i) Recruitment procedures

The screening registers maintained by the health assistants were used to collect data about the following:

- Number of patients who attended the PHC/CHC
- Number of patients ineligible for screening (with reasons)
- Number of patients who were screened
- Number of patients who screened positive for harmful or dependent drinking
- Number of patients who consented to participate in the trial
- Number of patients who refused participation in the trial (with reasons)

ii) Intervention delivery

The logbooks maintained by the counsellors were used to collect the following data:

- Number of drop outs from treatment
- Number of patients completing treatment
- Number of sessions
- Duration of the session
- Where the session was delivered
- Whether a significant other (SO) accompanied the patient for the session.

c) Q-CAP

The Q-CAP data was collected for each session tape rated during supervision. Data was available on ratings done by self (i.e. the counsellor whose tape was listened to during supervision), peer counsellors, and therapist.

10.2.12 Analyses

Analyses were carried out using Stata (version 14). Baseline characteristics of individuals who consented and did not consent, and participants who did and did not complete outcome assessments were compared. Baseline characteristics of participants in the CAP arm were compared with those in the EUC arm. These were presented as proportions or means as appropriate and compared using chi square test and t test respectively.

The process indicators were presented consistent with CONSORT guidelines (Moher et al., 2001) including a trial flow chart which showing total adult male PHC attendees during the period of the trial, total assessed for eligibility using the inclusion and exclusion criteria, number of patients meeting inclusion or exclusion criteria, number screened for eligibility, number consenting to enter the trial, and number refusing or excluded. The outcome measures were summarized at recruitment, and at three-months by intervention arm. These were summarised as means (standard deviation) or proportions as appropriate. Mean scores (and range) on the TSS and GS sub scales of the QCAP were calculated separately for the supervisors (therapists), the counsellor whose session was reviewed (self) and the rest of the counsellors (peers). Paired t-tests were then calculated to assess differences between the raters on mean subscale scores.

The primary analysis was intention-to-treat at the three-month end-points adjusted for baseline values, regardless of adherence to the treatment. Adjustments were made for baseline AUDIT. PHC was adjusted for as a fixed effect in the analysis to allow for within-PHC clustering. As there was only one counsellor per PHC additionally adjustment for counsellor variation was not done. Analysis of outcome was conducted using logistic regression for binary outcomes and linear regression for continuous outcomes. Effect sizes were reported as crude and adjusted Odds Ratio (OR) with 95% confidence intervals for binary outcomes, and mean differences and standardised mean differences with 95% confidence intervals for continuous outcomes. Subgroup analyses were conducted to examine the moderating effects of severity of AUD and treatment completion on treatment outcomes.

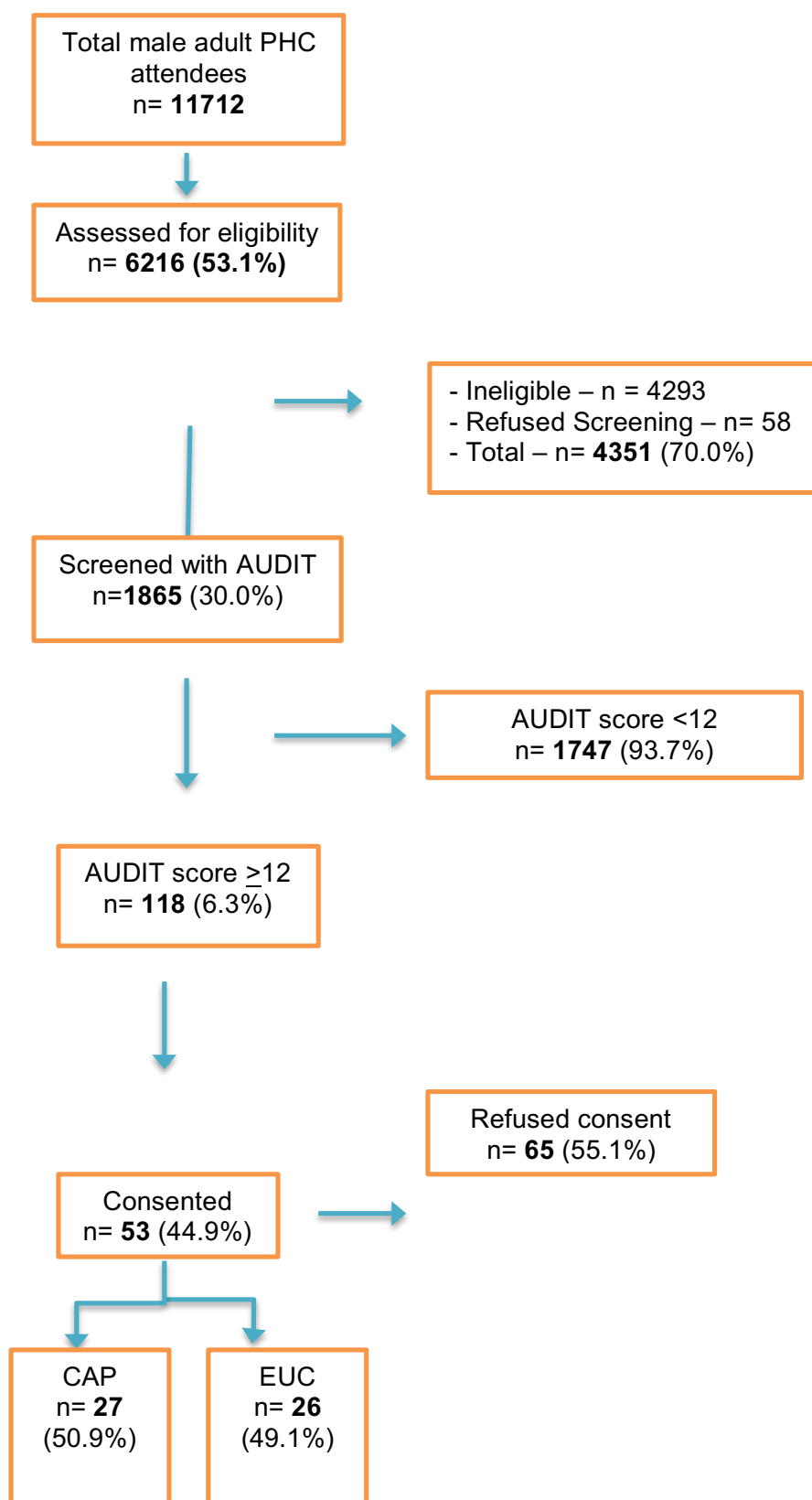
10.3 Results

10.3.1 Sample

The flow chart (Figure 10.2) describes the process of recruitment and follow-up of participants in the trial. For the duration of recruitment (3 months) for the pilot RCT, 11,712 adult men attended the 8 PHCs/CHCs. Of these, 6216 (53.1%) were assessed for eligibility in the pilot RCT. It was not possible to assess every adult male for eligibility, as some patients would go ahead and see the doctor and proceed home while others were getting screened. Of those assessed for eligibility, 70% were either ineligible or refused screening. Patients were not screened if they refused or were ineligible and the reasons were as follows: age more than 65 years of age (31.2%), the patient has already been screened (25.3%), age less than 18 years (16.8%), the patient was in a critical condition and unable to answer screening questions (7.7%), patient was not planning to stay at the same address for the duration of the pilot (6.1%), patient was residing outside the PHC catchment area (4.2%), patient had difficulty with hearing or speaking (3.1%), refused screening (2.2%), patient has already received or was receiving CAP (1.6%), patient was unable to fluently speak the vernacular or English (1.5%), or the patient was receiving psychiatric care for his AUD (0.2%). The reasons for refusal included the following: No time (46.2%), not interested in the study (29.2%), patient did not specify reason for refusal (15.4%), and other reasons (9.3%).

Of the 1865 male adults screened with the AUDIT 118 (6.3%) had harmful or dependent drinking (AUDIT score ≥ 12). 53 (44.9%) of these, consented to participation in the pilot RCT; 27 got randomised to the CAP arm and 26 to the EUC arm. In the CAP arm, 20 (74.1%) were harmful drinkers and 7 (25.9%) were dependent drinkers. In the EUC arm, 12 (46.2%) were harmful drinkers and 14 (53.9%) were dependent drinkers.

Figure 10.2: CONSORT diagram of pilot RCT of CAP



There was no significant difference between the consenters and non-consenters on mean AUDIT score, age, marital status, or educational status (Table 10.1). However there was a large amount of missing data among non-consenters.

Table 10.1: Socio-demographic profile of consenters and non consenters

Variable	Consenter n=53 (44.9%) n (%) or mean (SD)	Non consenter n=65 (55.1%) n (%) or mean (SD)	p
Mean age (SD) mv*=8	41.7 (11.2)	38.9 (11.4)	0.2
Marital status Married Never married/Post marital mv=32	44 (83.0) 9 (17.0)	26 (78.8) 7 (21.2)	0.6
Educational status Illiterate Literate mv=56	8 (15.1) 45 (84.9)	1 (11.1) 8 (88.9)	0.7
Employment status Unemployed Employed mv=56	7 (13.2) 46 (86.8)	2 (22.2) 7 (77.8)	0.5
Alcohol Use Disorder			0.6

Variable	Consenter n=53 (44.9%) n (%) or mean (SD)	Non consenter n=65 (55.1%) n (%) or mean (SD)	p
Harmful drinker	32 (60.4)	42 (64.6)	
Dependent drinker	21 (39.6)	23 (35.4)	
Mean AUDIT score	19.7 (6.9)	18.5 (6.0)	0.3

mv-Missing values

There was no statistically significant difference between the participants randomised to the CAP and EUC arms on mean AUDIT score, age, marital status, or educational status (Table 10.2). There were significantly higher harmful drinkers in the CAP arm than in the EUC arm (74.1% vs. 46.2%; $p=0.04$).

Table 10.2: Socio-demographic and clinical profile of the participants

Variable	CAP n=27 (50.9%) n (%) or mean (SD)	EUC n=26 (49.1%) n (%) or mean (SD)	p
Mean age (SD) mv*=4	41.4 (11.4)	42.0 (11.3)	0.9
Marital status			0.8
Married	22 (81.5)	22 (84.6)	
Never married/Post marital	5 (18.5)	4 (15.4)	
Educational status			0.5
Illiterate	5 (18.5)	3 (11.5)	
Literate	22 (81.5)	23 (88.5)	
Employment status			0.05
Unemployed	6 (22.2)	1 (3.9)	
Employed	21 (77.8)	25 (96.2)	
Alcohol Use Disorder			0.04
Harmful drinker	20 (74.1)	12(46.2)	
Dependent drinker	7 (25.9)	14 (53.9)	
Mean AUDIT score	18.5 (7.2)	20.8 (6.6)	0.2

10.3.2 The treatment process

Of the 27 participants in the CAP arm, 15 (55.6%) completed treatment and 12 (44.4%) dropped out of treatment. There was no statistically significant difference between the treatment completers and dropouts on AUD, mean AUDIT score, age, marital status, employment status or educational status (Table 10.3).

Table 10.3: Socio-demographic profile of treatment completers and dropouts

Variable	Treatment completer n=15 (55.6%) n (%) or mean (SD)	Dropout n=12 (44.4%) n (%) or mean (SD)	p
Mean age (SD) mv*=2	43.2 (12.1)	39.2 (10.6)	0.4
Marital status			0.4
Married	13 (59.1)	9 (40.9)	
Never married/Post marital	2 (40.0)	3 (60.0)	
Educational status			0.2
Illiterate	4 (80.0)	1(20.0)	
Literate	11 (50.0)	11 (50.0)	
Employment status			0.5
Unemployed	4 (66.7)	2 (33.3)	
Employed	11 (52.4)	10 (47.6)	
Alcohol Use Disorder			0.06
Harmful drinker	9 (45.0)	11 (55.0)	

Variable	Treatment completer n=15 (55.6%) n (%) or mean (SD)	Dropout n=12 (44.4%) n (%) or mean (SD)	p
Dependent drinker	6 (85.7)	1 (14.3)	
Mean AUDIT score	20.7 (8.7)	15.8 (3.3)	0.08

mv-Missing values

The mean number of patients per counsellor was 3.4 (Range 1-6). All participants in the intervention arm received the first session. 17 (63%) participants received session 2, 11 (40.7%) received session 3, and 4 (14.8%) received session 4. The total number of sessions delivered was 59 and the mean number of sessions per patient was 2.2 (Range 1-4). The treatment dropout rate was 44.4%.

Among treatment completers (n=15), 14 (93.3%) participants received session 2, 11 (73.3%) received session 3, and 4 (26.7%) received session 4. The total number of sessions delivered was 45 and the mean number of sessions per patient was 3 (Range 1-4). Among treatment drop-outs (n=12), 3 (25%) participants received session 2, and none received sessions 3 or 4. The total number of sessions delivered was 14 and the mean number of sessions per patient was 1.2 (Range 1-2).

The mean duration of the sessions ranged from 25.5 minutes to 42.6 minutes, the longest session being the first session. The first session was predominantly conducted in the PHC/CHC but as the sessions progressed, a higher proportion of sessions were conducted in the patients' homes (Table 10.4). None of the participants had to be referred out of the treatment because of physical and mental health problems.

Table 10.4: Details of CAP sessions

	Session 1	Session 2	Session 3	Session 4
	Mean (SD) or n (%)	Mean (SD) or n (%)	Mean (SD) or n (%)	Mean (SD) or n (%)
Mean duration in minutes (SD)	42.6 (14.0)	31.3 (17.9)	25.5 (14.7)	31.0 (9.8)
Setting				
Primary/Community Health Centre	23 (85.2)	9 (52.9)	5 (45.5)	1 (25.0)
Patient's home	4 (14.8)	8 (47.1)	6 (54.6)	3 (75.0)
Significant other present during the session	6 (22.2)	7 (50) mv*=3	1 (11.1) mv=2	1 (33.3) mv=1

*mv-Missing value

10.3.3 Evaluation of therapy quality

18 sessions were reviewed and rated in supervision during the course of the case series. Sessions of all 8 counsellors were reviewed during supervision. The proportion of sessions that were reviewed is as follows: Session 1 (n=9, 50%), Session 2 (n=6, 33.3%), Session 3 (n=2, 11.1%), and Session 4 (n=1, 5.6%). Table 10.6 describes the mean treatment-specific and general skills scores by supervisor, self and peers, and compares the differences in scores by each of these raters. The counsellor whose session tape was reviewed rated himself/herself higher than the supervisor or peers on the TSS subscale and higher than the supervisor on the GS scale. However these differences in ratings were not statistically significant.

Table 10.5: Competency evaluation of counsellors-Mean Differences of between Expert, Self and Peer Ratings

	Treatment Specific Skills (TSS) (n=18) Mean (Range)	General Skills (GS) (n=18) Mean (Range)		TSS Mean Difference (95% CI)	p	GS Mean Difference (95% CI)	p
Self Rating	2.25 (1.61-3.01)	2.4 (1.7-2.87)	Self vs. Supervisor	-0.15 (-0.45-0.15)	0.3	-0.06 (-0.34-0.21)	0.6
Supervisor Rating	2.1 (1.72-2.55)	2.33 (1.9-2.87)	Peer vs. Supervisor	-0.06 (-0.16-0.03)	0.2	-0.12 (-0.29-0.05)	0.1
Peer rating	2.17 (1.9-2.59)	2.46 (2.25-2.88)	Self vs. Peer	-0.08 (-0.35-0.19)	0.5	0.05 (-0.13-0.25)	0.5

10.3.4 Outcome evaluation

Of the 53 patients who entered the pilot RCT, primary outcome data was available in 47 (88.7%) participants. The mean follow up period was 85.1 days (Range 48-247 days; SD 47.6) and median follow up period was 69 days. There were no statistically significant differences between the outcome completers and dropouts on severity of AUD (harmful or dependent drinkers), mean baseline AUDIT score, age, marital status, employment status or educational status. Among those in the CAP arm, compared to treatment dropouts, participants who completed treatment were also significantly more likely to complete outcome evaluation (100% vs. 66.7%; $p=0.02$).

Table 10.6: Predictors of availability of primary outcomes

Variable	Primary outcome measured n=47 (88.7%) n (%) or mean (SD)	Dropout from outcome evaluation n=6 (11.3%) n (%) or mean (SD)	p
Mean age (SD) mv*=4	41.5 (11.6)	44.0 (5.9)	0.7
Marital status			0.1
Married	39 (88.7)	5 (11.4)	
Never married/Post marital	8 (88.9)	1 (11.1)	
Educational status			0.3
Illiterate	8 (100.0)	0 (0)	
Literate	39 (86.7)	6 (13.3)	
Employment status			0.3

Variable	Primary outcome measured n=47 (88.7%) n (%) or mean (SD)	Dropout from outcome evaluation n=6 (11.3%) n (%) or mean (SD)	p
Unemployed	7 (100.0)	0 (0)	
Employed	40 (87.0)	6 (13.0)	
Alcohol Use Disorder			0.2
Harmful Drinker	5 (15.6)	27 (84.4)	
Dependent Drinker	1 (4.8)	20 (85.2)	
Mean baseline AUDIT score	20.2 (7.1)	15.2 (3.4)	0.09

Table 10.7 describes the effectiveness of CAP. Compared to EUC, there were better drinking outcomes in the CAP arm. The mean AUDIT score and mean alcohol consumed in past two weeks was lower in the CAP arm as compared to EUC. CAP also led to greater mean reduction in the AUDIT score compared to EUC. Participants in the CAP arm had a higher odds of being abstinent at follow up compared to those in the EUC arm. Finally, participants in the CAP arm had less severe impact of their drinking (mean SIP score) compared to participants in the EUC arm. None of these differences were statistically significant, although the effect on AUDIT scores was tending towards statistical significance at $p=0.05$.

10.3.5 Sub group analyses

Table 10.8 describes the effectiveness of CAP separately based on the severity of AUD i.e. harmful drinkers and dependent drinkers and the effectiveness of CAP in treatment completers.

1) By drinking severity

a) Harmful drinkers

The mean AUDIT score and mean alcohol consumed in past two weeks was lower in the CAP arm as compared to EUC. CAP led to greater mean reduction in the AUDIT score compared to EUC. Participants in the CAP arm had a higher odds of being abstinent at follow up compared to those in the EUC arm. Finally, participants in the CAP arm had less severe impact of their drinking (mean SIP score) compared to participants in the EUC arm. None of these differences were statistically significant.

b) Dependent drinkers

The mean AUDIT score was lower in the CAP arm as compared to EUC. CAP led to greater mean reduction in the AUDIT score compared to EUC. Participants in the CAP arm had a higher odds of being abstinent at follow up compared to those in the EUC arm. Finally, participants in the CAP arm had less severe impact of their drinking (mean SIP score) compared to participants in the EUC arm. The mean alcohol consumed in past two weeks was higher in

the CAP arm as compared to EUC. None of these differences were statistically significant.

2) Treatment completers

The mean AUDIT score was significantly lower in the CAP arm as compared to EUC. CAP led to greater mean reduction in the AUDIT score compared to EUC. Participants in the CAP arm had a higher odds of being abstinent at follow up compared to those in the EUC arm. This was tending towards statistical significance at a p value of 0.06. Finally, participants in the CAP arm had less severe impact of their drinking (mean SIP score) and had consumed lesser alcohol in the past two weeks as compared to EUC. However, these latter differences were not statistically significant.

Table 10.7: Effect of CAP on drinking and other outcomes

Outcome	CAP (n=23) Mean (SD) or n (%)	EUC (n=24) Mean (SD) or n (%)	Adjusted difference or Ratio (95%CI) ^a	mean Odds	p-Value
Mean AUDIT score	10.5 (10.0)	16.9 (8.3)	-4.9 (-10.1-0.2)		0.06
Mean change in AUDIT score	-8.8 (10.5)	-4.3 (7.0)	-5.1 (-10.3-0.2)		0.06
Mean alcohol (gms) consumed in past 2 weeks	311.8 (541.6)	548.4 (681.7)	-145.8 (-526.4-234.9)		0.4
Abstinent (Not consumed any alcohol in past 2 weeks)	9 (40.9)	5 (22.7)	2.4 (0.4-15.5)		0.4
Mean SIP score	7.1 (11.7)	14.8 (15.3)	-4.7 (-11.8-2.4)		0.19

^aAdjusted for PHC and baseline AUD

Table 10.8: Effect of CAP on drinking and other outcomes (Sub-group analyses by drinking severity and treatment completion)

Outcome	Harmful Drinkers		Dependent Drinkers		Treatment Completers	
	Adjusted mean difference or Odds Ratio (95%CI) ^a	p	Adjusted mean difference or Odds Ratio (95%CI) ^a	p	Adjusted mean difference or Odds Ratio (95%CI) ^a	p
Mean AUDIT score	-3.8 (-11.3-3.6)	0.3	-3.3 (-15.6-8.9)	0.6	-6.8 (-12.3- -1.4)	0.02
Mean change in AUDIT score	-4.1 (-11.7-3.5)	0.3	-3.3 (-15.6-8.9)	0.6	-7.0 (-12.5- -1.5)	0.01
Mean alcohol (gms) consumed in past 2 weeks	-331.0 (-923.0-261.0)	0.3	336.7 (-759.2-1432.6)	0.5	-159.6 (-613.6-294.4)	0.5
Abstinent (Not consumed any alcohol in past 2 weeks)	2.0 (0.3-15.6)	0.5	2.4 (0.3-21.3)	0.4	4.0 (0.9-17.0)	0.06
Mean Short Inventory of Problems (SIP) score	-1.1 (-8.7-6.6)	0.8	-9.4 (-30.2-11.4)	0.3	-6.4 (-14.5-1.7)	0.1

^aAdjusted for PHC and baseline AUD

10.4 Output

To summarise the results, we learnt that it was possible to efficiently implement RCT specific processes within the PHC. Among those screened on the AUDIT, about a quarter of those with a score of 12 and above were dependent drinkers. Except for the imbalance in the two arms of the trial with regard to proportion of harmful drinkers (higher proportion of harmful drinkers in the CAP arm and higher proportion of dependent drinkers in EUC arm) there were no other differences between the two arms. Similarly, there were no differences between the consenters and non-consenters. Furthermore, although there was a relatively high dropout rate from treatment there were no differences between treatment completers and non-completers on socio-demographic or drinking parameters. On an average, patients received the optimal number of two sessions, with completers receiving, on an average, more sessions (three) than drop outs (one); and most dropouts happened after session 1. The first session was predominantly conducted in the PHC/CHC but as the therapy progressed, a higher proportion of sessions were conducted in the patients' homes. There were no significant differences between quality ratings given during supervision by self, peers and experts. There were no statistically significant differences between the follow up outcome completers and dropouts; except among those in the CAP arm, compared to treatment dropouts, participants who completed treatment were also significantly more likely to complete outcome evaluation. Although all the outcomes were better in the CAP arm the findings were not statistically significant. This was also true when the outcomes were separately analysed for dependent and harmful drinkers. Finally, among treatment completers, compared to EUC, the mean AUDIT score was significantly lower and the mean reduction in the AUDIT score was greater in the CAP arm. In that same subgroup there was greater abstinence in the intervention arm compared to the control arm and this was tending towards significance. Even though statistically insignificant, the pattern of findings (i.e. reduction in AUDIT scores, increased abstinence, but non significant differences in amount of drinking) indicate that although there was an increase in non risky drinking/abstinence in the intervention arm as compared to the control arm, among those who continued to drink there was not much reduction in the amount of drinking.

This was the final step of the intervention development process and there were several lessons to learn from it. Some of the findings reinforced the lessons learnt in the previous steps and other findings allowed us to refine the procedures for the definitive RCT. One of the goals of this step was to refine the procedures for the definitive RCT. We were successful in efficiently implementing procedures related to screening, randomisation, concealment of allocation, blinding, and data collection and entry. It was important to test these procedures as a lot of these procedures e.g. screening, outcome data collection were done electronically using tablet PCs to collect data and then electronically transferring the data to the server. This incoming data was electronically transferred into the database, thus reducing the chances of human error in data entry. It was important to test these procedures before the definitive RCT started as some of them (data transfer to the server) relied on mobile service providers and if the procedures failed we needed to have back up systems to ensure efficient data collection and storage. The pilot RCT demonstrated that the procedures were sufficiently fool proof to implement in the definitive RCT.

Our finding in the case series that a large proportion of those with an AUDIT score of more than 12 are dependent drinkers was borne out in the pilot RCT as well. This further justified our decision to include dependent drinkers in the target group, although the plan in the definitive RCT is to do a primary analysis only of the harmful drinkers. However, in this pilot RCT we randomised both harmful and dependent drinkers, as we were primarily interested in testing procedures rather than the impact of the intervention. Doing that resulted in an imbalance in the two arms with regard to type of AUD, despite randomisation but this was to do with the small sample size rather than any flaw in the randomisation procedures. Some other findings that reinforced our observations in the case series included relatively high rate of dropout but there not being any major differences between dropouts and treatment completers; and that on an average patients received what was conceptualised as optimal treatment (i.e. 2 sessions).

It was encouraging to see that patients were enthusiastically taking on the option of sessions delivered at home after the first primary care based session. If the CAP intervention is found to be cost effective then this would have major implications as one of the major barriers to access to healthcare in India is the

long distances that people have to travel to get to health facilities. Moving healthcare from such facilities and taking them to the patients' doorstep effectively overcomes this major barrier. Similarly, another barrier to scale up of an intervention is the difficulty in maintaining its quality in the absence of supervision by experts. As in the case series, in the pilot RCT as well we were able to demonstrate that there are no significant differences between peer counsellors and experts when they rate therapy quality. This further demonstrates the validity of peer supervision that is a more realistic model of supervision for scaling up, as it does away with the need for an expert supervisor.

Finally, one of the secondary aims of the pilot RCT was to evaluate preliminary evidence of effectiveness. We found that outcomes were better in the CAP arm, overall as well as separately in dependent and harmful drinkers. However the findings were not statistically significant. Among treatment completers, though there were significantly better drinking outcomes in the CAP arm compared to EUC. Thus, we found preliminary evidence of impact of the intervention. It is important to note that the pilot RCT was not powered to test the effectiveness hypothesis and the finding from this study has to be interpreted as evidence that the CAP has the potential to be effective and would be worth testing in a definitive RCT. Finally, the finding from the sub group analysis of treatment reinforced the importance of treatment completion and ensured that processes were implemented to enhance retention in treatment in the definitive RCT.

Thus, at the end of this step of the intervention development process we had data about process indicators (e.g. recruitment rates) needed to inform the definitive RCT procedures and also refined the procedures for the definitive RCT (e.g. randomisation). We had data that indicates the potential scalability of CAP e.g. peer group supervision, and we had evidence of preliminary impact of the CAP intervention, and information about potential moderators of intervention effect. This is the final step of the PREMIUM intervention development process and in the concluding chapter of my thesis I will summarise this process and the outcome i.e. the CAP intervention, implications of the process and the outcome, and the strengths and weaknesses of the same.

Chapter 11: Discussion

In the preceding chapters (Chapter 2 to Chapter 10) I have described the systematic process that was followed to develop the Counselling for Alcohol Problems (CAP), a culturally and contextually appropriate intervention for harmful drinking to be delivered by lay counsellors in primary care in Goa. In this chapter I will do the following: a) Summarise the CAP intervention and its place in the landscape of interventions for harmful drinking; b) Summarise the PREMIUM intervention development process and compare it with other treatment development models; c) Examine the strengths and limitations of the PREMIUM intervention development process; and d) Highlight the implications of the PREMIUM intervention development process and CAP for future research, clinical practice, and policy.

11.1 The Counselling for Alcohol Problems intervention

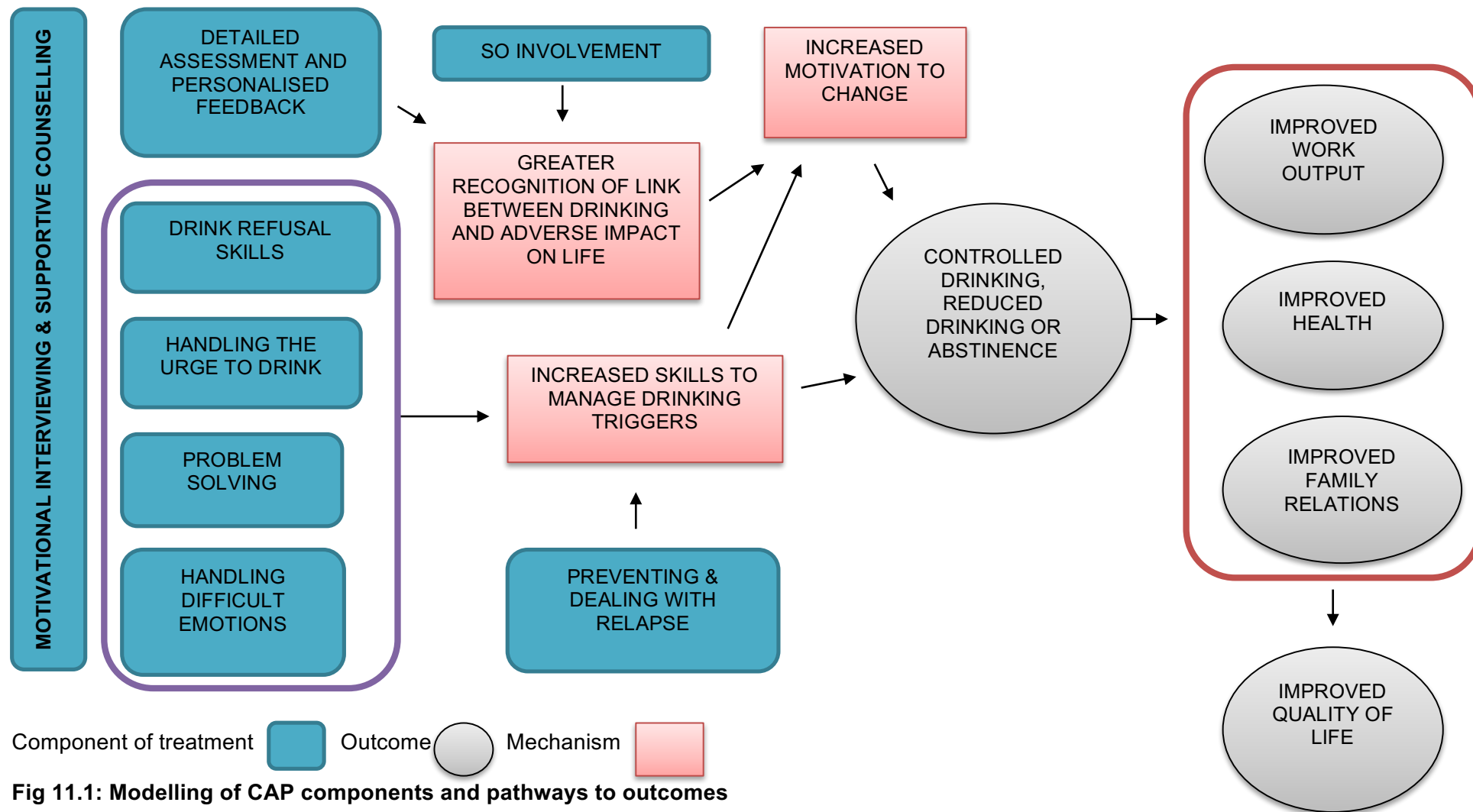
11.1.1 The final intervention package (Extract from Nadkarni et al., 2015)

The CAP intervention is designed to be delivered to harmful drinkers in three phases. In the 'initial phase' the counsellor helps the patient understand the problems his drinking may be causing and may need to change. This is done through a detailed assessment followed by personalised feedback. This is then used to facilitate a commitment to change from the patient which in turn is used to generate a 'change and action plan' which summarises what the patient wants to do to change his drinking and its related problems, and the actual actions that the patient will take to achieve this goal. In the 'middle phase' the counsellor helps the patient to develop 'thinking and behavioural' skills and techniques (drink refusal, handling drinking urges, problem solving and handling difficult emotions) that will allow the patient to make the changes that he desires. In the 'ending phase' the patient learns how to manage potential or actual relapses using these 'thinking and behavioural' skills and techniques. The common thread that runs across these phases is the counselling style of the counsellor, and that is informed by Motivational Interviewing (MI) and supportive counselling.

CAP is delivered over a maximum of four sessions, one session being considered a minimum requirement and two sessions being optimal. The sessions should ideally be delivered at a weekly to fortnightly frequency. Each session lasts 30 to 50 minutes and can span one or more 'phases' of CAP. For example, if a patient entering treatment is not ready for change then the complete first session would be focused on 'initial phase', but if a patient enters treatment ready for change then the counsellor could quickly move through the 'initial phase' in session 1 and proceed to the 'middle phase' in the same session. There is flexibility in where the intervention could be delivered based on the mutual convenience of the patient and the counsellor. The intervention could be delivered in the primary care clinic, patient's home, or in any other convenient but safe place (e.g. friend's home, village temple). Involving a significant other (SO) in the treatment is optional. It is recommended that the SO should be engaged as far as possible in the first session to get a better understanding of the patient's drinking and its impact, and also to help in developing a change plan. However, subsequent involvement of the SO may be encouraged based on how helpful the involvement was; and the patient and the counsellor should decide this collaboratively. Finally, the use of the information booklet is strongly recommended as it helps the patient engage with the treatment in between sessions. Thus the CAP has an inbuilt flexibility not just in what is delivered (i.e. the strategies used), but also in other aspects like where it is delivered (i.e. clinic, home, or any other alternative place), how it is delivered (i.e. phasic delivery), and who is involved in the treatment process (i.e. SO involved or not).

Fig 11.1 illustrates these various components of CAP and a proposed mechanism through which they would lead to a change in the drinking outcomes and the eventual bio-psycho-social outcomes. Supportive counselling and MI strategies are used throughout the course of the treatment and help to engage and increase the motivation of the patient. The detailed assessment and personalised feedback along with SO involvement in treatment is postulated to increase the patient's motivation to change by facilitating the patient's recognition of the link between his drinking and the resultant adverse impact on his life. Furthermore, the process of reporting one's own drinking and subsequent personalised feedback leads to reflection on one's own behaviour

and may initiate self-monitoring. This in turn may lead to cognitive dissonance where the drinker recognises inconsistencies between current drinking and a personal standard, leading to change in drinking behaviour. Once the patient makes a decision to change his drinking behaviour, the various 'thinking and behavioural' skills will increase his capacity to manage drinking triggers which in turn will further increase his motivation to change and help him achieve his drinking goals, as well as help in managing lapse and relapse. The achievement of the patient's drinking goals will then have a positive effect on the various domains of his life and eventually the overall quality of his life. This treatment development process was not designed to test these propositions and future research on the CAP intervention will need to examine these mechanisms in detail.



11.1.2 *Mapping CAP to the existing evidence base*

The World Health Organisation (WHO) recommends 'brief counselling' for the treatment of harmful drinkers. This includes giving brief advice, assessing and tailoring advice to stage of change, providing skills training using a self-help booklet if needed, and follow up (Babor and Higgins-Biddle, 2001). Consistent with those recommendations, there is substantial high quality evidence to support the effectiveness of such interventions delivered in primary care for hazardous and harmful drinkers (Kaner et al., 2009). More specifically, for harmful drinkers, evidence from individual studies and from recommendations derived from extensive reviews of the evidence support the use of interventions that are brief, single or multi contact, and based on strategies focused specifically on motivation building, cognitions, behaviour, problems, and social networks related to alcohol (D'Onofrio et al., 2012; Pilling et al., 2011; Whitlock et al., 2004). To summarise, multi-contact interventions for harmful drinkers in primary care settings, have been recommended to have the following elements: screening, assessment and feedback, advise to reduce alcohol, agree on individual drinking goals, support to build motivation, self-help skills needed for behavior change, follow-up support, and referral of dependent drinkers for specialty treatment (US Preventive Services Task Force, 2004). The CAP intervention maps well to this template as it has a core focussed on building motivation, around which there are components aimed at providing skills which empower the harmful drinker to make changes in his drinking behaviour.

However, these recommendations are informed by interventions that have been developed and tested in developed countries from Europe and North America, and Australia. Very few trials have tested psychosocial interventions for hazardous or harmful drinkers in Low and Middle Income Countries (LMIC). A Randomised Controlled Trial (RCT) from Brazil demonstrated that Brief Intervention (BI) was effective in reducing risky drinking in university students (Simão et al., 2008), and a non-randomised trial in India reported effectiveness of a BI based on MI in a mix of hazardous, harmful and dependent drinkers (Pal et al., 2007). However neither of these was relevant to the PREMIUM context, as specialists delivered the intervention that was tested. In LMICs only two published RCTs have tested a Non Specialist Health Worker (NSHW) delivered treatment for any form of alcohol use disorder (AUD); one a primary care based

study from Thailand testing Motivational Enhancement Therapy (MET) delivered by nurses to hazardous drinkers (Noknoy et al., 2010) and the other a HIV clinic based study from Kenya, testing Cognitive Behaviour Therapy (CBT) delivered by lay counsellors to hazardous or binge drinkers (Papas et al., 2011). In the RCT from Thailand, the sample contained harmful drinkers but the intervention was based on the Project MATCH MET manual and did not have any contextual adaptations, either to make it suitable for delivery by NSHWs or to make it acceptable to the recipients. However, one could argue that the intervention did not need any contextual adaptation as proven by the fact that it was effective in its original form in this RCT. The exploratory RCT from Kenya tested CBT that was contextually adapted through a systematic process and tested in hazardous/binge drinkers and could have included harmful drinkers. Although this intervention comes the closest to the CAP intervention in terms of the development process and delivery agents, it was not developed specifically for harmful drinkers or delivered in primary care. This highlights the importance of CAP on the background of a dearth of contextually relevant interventions for harmful drinking suitable to be delivered by NSHW in primary care in LMICs. To put this in context, the CAP intervention is arguably the first contextually appropriate intervention for harmful drinking developed using a systematic treatment development process and developed specifically to be delivered by lay counsellors in primary care.

11.1.3 Cultural adaptations of MI

Over the years, MI has been adapted in several ways. This is consistent with the recommendations made by one of the originators of MI, William Miller, that such research on cultural adaptations of MI is important for the development of optimal approaches in the delivery of MI (Miller et al., 2007). The adaptations have primarily been made to increase the access of MI to different cultural groups (e.g. Latinos, Hispanics), and range of disorders (e.g. smoking, cancer related fatigue, glaucoma, obesity, depression, intellectual disability, HIV), to match different delivery mechanisms (e.g. telephone, group setting) and to achieve a range of goals (e.g. reduce drinking, weight loss, smoking cessation, compliance with self care advice, treatment adherence) (Allen et al., 2011; Field et al., 2015; Field and Caetano, 2010; Frielink and Embregts, 2013; Interian et

al., 2010; LaBrie et al., 2007; Lee et al., 2013; Petersen et al., 2007; Ream et al., 2015; Rusch and Corrigan, 2002) .

Some of the cultural adaptations that have been made to increase the acceptability of MI include giving feedback about the types, and intensity of acculturative stress drinkers may experience and its role in drinking, integration of family, and community as reasons for change, initiation of discussion on how social context and family dynamics may affect drinking, role of social pressures (e.g., cultural gatherings) to engage in heavy drinking, encouragement to identify, and actively engage respected family and community members as helpers in efforts to change their drinking, including information about foods and physical activities commonly used in the Latino culture, using a Spanish-speaking interventionist, and conducting the intervention at a local Latino community organization (Abdull et al., 2014; Allen et al., 2011; Field et al., 2015; Field and Caetano, 2010; Castro et al., 2014; Corsino et al., 2012; Interian et al., 2010; Lee et al., 2013; Petersen et al., 2007; Ream et al., 2015; Rusch and Corrigan, 2002). Although such adaptations are not many, the limited evidence available demonstrates that the adaptations are effective, feasible and acceptable.

It is important to understand why cultural adaptations of MI are necessary to enhance its effectiveness. MI emphasises on patient values by aligning behavior change within the context of personal ideals and goals. Hence, successful application of MI is predicated on an understanding of the values that are relevant for individuals in a particular social context. This might include understanding the value conflicts that are experienced while drinking. Finally, one could speculate why MI could be a good fit for developing societies like India. In many developing countries large sections of the populace experience a significant power difference in society, as well as in accessing therapy. Therefore, it could be hypothesised that when patients experience an empowering and respectful therapeutic approach like MI, it has a more powerful effect on moving the recipient towards positive change.

11.1.4 *Major lessons learnt*

Research over the years has identified a range of barriers that impede engagement with services in low resource settings. These include factors like financial constraints, inadequate transportation, lack of community-based service providers, and patients' expectations barriers e.g. lack of understanding of diagnosis, treatment goals or nature of the treatment, a preference for a more medical model or a directive authoritarian approach (Al-Krenawi and Graham, 1999; Al-Krenawi et al., 2000; Eapen and Ghubash, 2004; Karam et al., 2006; Murray et al., 2006; Schwartz et al., 2002). Strategies that have been used in low resource settings to overcome these barriers include delivering new services through existing platforms of care e.g. primary care, partnerships with non governmental agencies, incorporation of concrete strategies (such as relaxation training) rather than more abstract ones, use of home visits, directive clinical strategies, and employing local service providers who are familiar with local cultural norms (Al Eissa and Almuneef, 2010; Al-Krenawi and Graham, 1999; Al-Krenawi et al., 2000; Bader et al., 2007; Eapen and Ghubash, 2004; Mohammadi et al., 2008; Savaya, 1998; Schwartz et al., 2002).

We anticipated some of these fundamental contextual challenges at the outset and the foundations of the CAP intervention were planned to overcome these challenges e.g. delivery of the intervention by NSHW, and integrating the intervention in the primary care platform. On the other hand, there were several lessons that were learnt along the way and these led to adaptations and modifications made iteratively during the course of treatment development aimed at overcoming environmental and individual level barriers. Some of these lessons were centred on preconceived cultural notions that were challenged at various stages of the treatment development process. One such notion was related to the socio-centric nature of the Indian society that led us to believe that psychosocial strategies related to working as groups or family dyads would intuitively be better suited for Indian settings. However this was not borne out during the treatment development process as 'support groups' were excluded by local experts in the Treatment Development Workshops, the involvement of the SO was sometimes reported as unhelpful by the counsellor as well as the

patient, and the involvement of the SO in treatment did not necessarily lead to better outcomes in the case series (although the case series was not powered to definitively answer this question). An important lesson from this for future research is that cultural assumptions should not be taken for granted and need to be tested out in formative research.

Another major lesson was related to the core intervention strategy viz MI. It was extremely challenging to deliver MI and to achieve an acceptable level of competency, not just for the lay counsellors, but also for the 'therapists'. The 'therapists' found it challenging despite having several years of experience of working as clinicians in the mental health field. There could be several reasons behind these, those related to MI itself, those related to the delivery agents, and those related to the recipients. It could well be that MI as a psychosocial intervention strategy appeared conceptually simple, but deceptively so when it came to delivery. It is not difficult to understand why clinicians, trained in a system that promotes the paternalistic physician model, would find it challenging to acquire a new skill that is based on patient autonomy. It is proposed that clinicians practising MI acquire expertise in the skill through eight sequential stages, the first one being 'openness to collaboration with clients' own expertise' (Miller and Moyers, 2006). This in turn would mean that clinicians struggling with the first stage itself would have difficulties in achieving the subsequent stages required to achieve competency. Finally, for patients who have been conditioned to receive paternalistic advice from health professionals it was difficult to effectively engage with a clinician who would give them the decision-making reins in the therapeutic relationship. All of these factors together could have potentially interacted with the challenges encountered in delivering MI and consequently achieving suitable competencies.

Another major lesson was related to the selection of the target group for the intervention. Although harmful drinking causes significant burden, a lot of the effects of the harmful drinking are not visible, at least to the external observer. On the other hand, the effects of alcohol dependence, the more severe type of AUD, are more visible. Attempting to provide a service for the less visibly unwell, while the more visibly unwell only get limited services, is problematic at several levels. It interferes with effective engagement with the health system, as

well as the community, as the programme delivering the intervention is perceived to be responsive to its own requirements rather than to the needs of the community. Furthermore, such an approach also runs counter to the notions of equity and justice. The lesson for the future, while designing programmes for the less severely unwell end of a disorder spectrum, is to also cater concurrently to the more severely unwell. At the very least it should involve structured referral of the latter to specialist care; although this is problematic if such care does not exist, or is severely limited.

Another lesson is that successfully delivering a psychosocial intervention in low resource settings involves taking it out of health facilities and moving it into the community. Primary care facilities by virtue of being the most commonly used health facility could be used as a platform to identify patients with the target disorder, as was done with PREMIUM. However, for an intervention made up of multiple sessions, some of the biggest barriers to access in LMIC are the lack of time, money and transportation facilities. For such interventions, taking the intervention to the patient's doorstep through home-visits or using technology (e.g. telephone) would be the best solutions to overcome access barriers.

Controlled drinking as a treatment goal was introduced into the CAP intervention after extensive deliberation. However, it was observed during supervision that the counsellors were not able to implement it as effectively as envisioned, despite adequate training. They were assertive in promoting abstinence as a goal but were not equally assertive in exploring the controlled drinking goal when patients indicated (sometimes indirectly) that they would prefer reducing their drinking than stopping completely. There could be several reasons for this. It is possible that helping the patient to plan and execute a controlled drinking plan is beyond the capacity of non-specialist health workers. It is also possible that the lay counsellors' belief systems about drinking (reflective of the predominant thinking in Indian society) sub consciously restricted them from offering controlled drinking as a goal equal to abstinence. Finally, the family dynamics around drinking (i.e. SO wanting abstinence while patient preferred controlled drinking), as seen in the formative research phase, could have acted as a deterrent in effective exploration of controlled drinking as a realistic goal.

One important question is whether CAP is suitable to be delivered by NSHW as its core is MI, a sophisticated style of counselling that appears deceptively simple. It is a crucial question as the potential scalability of CAP rests on it being suitable to be delivered by NSHW, the more cheaper and easily available manpower in low resource settings. Although there is no direct way of answering this question, there are several indirect ways in which it could be addressed. The qualitative interviews with the counsellors and the patients indicated that they were comfortable with what was being delivered. The supervision sessions and Q-CAP scores indicated that counsellors delivered what they were supposed to deliver up to a reasonably adequate quality. The final proof of the pudding would be the effectiveness of the CAP intervention as tested in the definitive RCT. If we find that the CAP is effective in reducing harmful drinking then that would indirectly indicate that it is suitable to be delivered by NSHW. However, if we find that it is not effective then the big question would be whether CAP by itself is ineffective or whether it is ineffective because it is unsuitable to be delivered by NSHW.

Cultural adaptations of interventions occupy the space between an 'universal approach' which views interventions as applicable to all cultures, and a 'culture-specific approach' that emphasises the importance of unique values, beliefs, traditions, and practices of cultures in the development of culturally grounded interventions (Falicov, 2009). A close examination of the content of the CAP intervention shows us that the components that make up the intervention are not different from those that are effective in Western cultures. What differs are the changes that have been made to the delivery systems to increase its accessibility. Thus the process used for developing CAP could be called "cultural attunement" which refers to changes made to evidence-based interventions to boost engagement and retention of cultural groups in treatment (Falicov, 2009). This includes changes made to the process of intervention delivery such as providing services in the patients' native language, and increase their comfort in sustained participation (e.g. delivering treatment at home). This means that CAP was an outcome of surface structure adaptation which did not require changes in core intervention components which affect therapeutic change and thus could also be re-engineered to work in other cultures with necessary surface adaptations.

Finally, one major lesson came from the peer supervision process. Effective supervision of practitioners is a key quality assurance tool in psychosocial intervention delivery (Schoenwald et al., 2013; Waltz et al., 1993) and conventional paradigms recognise experts as the gold standard in assessing the quality of intervention delivered (Townend et al., 2002). However, we were able to demonstrate that with sufficient experience, the peer group was able to provide as good quantitative feedback about therapy quality as the expert supervisors. This has major implications for the potential scalability of the CAP intervention. One of the major challenges to the scalability of psychosocial interventions is the sustainability of quality of the therapy in the absence of expert supervision, the reality of low resource settings. However, if well trained lay counsellors are able to supervise each other equally well as experts then it would be possible to scale up psychosocial intervention programmes in which the quality of therapy could be sustained without the need of an already overstretched and expensive expert human resource. Even though I argue that it is possible to develop a quality control system based on peer supervision the key lies in being able to do this in a sustained manner. In the case series with counsellors (Chapter 9), pilot RCT (Chapter 10) and the definitive RCT we observed that in the absence of refresher training, counsellor competencies tended to drift downwards. We also observed that there was differential progress in terms of sustained competencies, with improved competencies over time in some counsellors and static or reducing competencies in others. Table 11.1 summarises the mean scores on the treatment specific and general counselling sub scales of Q-CAP in the case series with counsellors (Chapter 9), and pilot RCT (Chapter 10). To summarise, the counsellors do better on the delivery of general counselling than on the treatment specific strategies, their skills improve over time, over time there is a better convergence of supervisor and peer ratings, and there is a variability in the competencies of the counsellors. This has several implications for the scalability of CAP such as appropriate selection of counsellors to ensure suitability for delivering counselling, intensive training, sustained competency evaluations, and intermittent refresher trainings.

Table 11.1: Q-CAP scores of the counsellors in case series and pilot RCT

	Treatment specific skills				General counselling skills			
	Case series with counsellors		Pilot RCT		Case series with counsellors		Pilot RCT	
	Supervisor Rating	Peer Rating	Supervisor Rating	Peer Rating	Supervisor Rating	Peer Rating	Supervisor Rating	Peer Rating
Counsellor 1	1.56	1.74	2.00	2.24	2.20	1.78	2.40	2.72
Counsellor 2	2.22	2.04	2.65	2.66	2.80	2.42	2.87	2.88
Counsellor 3	2.39	2.34	2.00	2.41	2.65	2.58	1.90	2.56
Counsellor 4	1.94	2.57	2.03	2.18	2.55	2.69	2.20	2.39
Counsellor 5	1.18	1.11	2.17	2.22	2.55	2.65	2.30	2.38
Counsellor 6	2.47	2.47	2.08	1.79	2.65	2.42	2.30	2.23
Counsellor 7	1.32	2.34	2.13	2.30	1.70	2.48	2.45	2.59
Counsellor 8	1.92	2.02	1.87	2.04	2.55	2.44	2.33	2.23

To summarise, there are several lessons to be learnt from the development of the CAP intervention and many of these would transcend the PREMIUM programme and inform other psychosocial intervention programmes to make them more efficient and successful.

11.2 The PREMIUM treatment development process

11.2.1 The proposed treatment development framework

Table 11.2 summarises the PREMIUM treatment development framework described in my thesis using the development of the CAP intervention as a case study (Nadkarni et al., 2015). As described in Chapter 1, the PREMIUM treatment development process is informed by several sources and the broader goal of the process, besides developing a contextually appropriate treatment for harmful drinking, was to codify a framework that could be used across a range of low resource settings to develop psychosocial interventions suited for that particular context. The framework (represented graphically in Fig 11.2) is sequential with four broad phases as follows 1) Understanding the available evidence and identifying gaps in the evidence, 2) Proposing a theory about how the intervention might eventually work, 3) Assessing acceptability and feasibility of the intervention, and 4) Fine-tuning procedures for evaluation.

Across these broad phases there are specific steps which are aimed at first identifying the components of the intervention, assembling them together into a coherent intervention, refining it through preliminary testing, and refining procedures for the definitive evaluation of the new intervention. In the first phase that aims to identify available evidence of existing interventions for the target disorder the starting point is the identification of an existing high quality systematic review and update it if required. In the unlikely circumstance that a recent high quality systematic review cannot be identified a new systematic review will have to be conducted. The global evidence then needs to be supplemented by local/regional evidence and this might also have to be sourced from grey literature as a lot of evidence generated in low resource settings never gets published in peer reviewed journals. Sourcing such material allows the paradigm of practice-based evidence to complement evidence-based practice. Although the nature of some of this work might mean that it has low

internal validity, it has high external validity because of greater proximity to routine practice.

A better understanding of the local explanatory models must be sought through a systematic review of the literature (if a relevant one does not already exist). If this is inadequate to provide information needed for the intervention development then it must be supplemented by qualitative research with the target group to fill gaps in the review findings. The various potential components of the intervention identified from these steps should then be filtered based on feedback from local stakeholders to identify those components that would be most feasible and safe for delivery by NSHWs and acceptable by the target group in that particular contextual setting. The filtered components that meet the criteria for acceptability, feasibility, perceived effectiveness, and safety should then be used to put together the framework of the new intervention based on input from local and international experts. Mental health professionals and NSHWs should then sequentially deliver this preliminary version of the intervention to the target group with the aim of iteratively refining the intervention content and delivery processes. The final version of the intervention obtained from this process should then be tested in a pilot RCT to evaluate the preliminary impact of the intervention and fine-tune the procedures for the eventual definitive RCT.

Thus the PREMIUM framework for the development of contextually appropriate psychosocial interventions ensures that due consideration is given to the context in terms of the socioeconomic and cultural background, the health system, the nature of the problem that is being targeted, and the mechanisms by which the intervention works. A highly effective intervention is practically useless in the real world if it is not possible to deliver it, if it does not engage the target group (both the recipients and the delivery agents) and cannot improve access, as it cannot be widely implemented. Hence, the PREMIUM treatment development framework addresses two primary questions, namely the feasibility (how logistically possible it is to deliver), and acceptability (whether service users and providers find the intervention acceptable to deliver and receive). Both of these are important and complementary attributes of an intervention that would influence its eventual scalability (the extent to which the intervention could be delivered to a much larger population).

Although each of the chapters from Chapter 2 to Chapter 10 serves a specific purpose and forms an important piece of the jigsaw puzzle, one could argue that Chapters 2-7 are good standalone studies but do not add much to the treatment development process (Fig 11.2). One could further argue that the steps described from Chapter 8-10 are the ones that contribute to the treatment development, independent of the preceding steps. My contention is that each of the steps of the treatment development process had a specific role to play and was crucial in increasing the confidence in the validity of the CAP intervention by mutually complementing each other. More specifically, while Chapters 2 and 3 helped identify evidence based and/or contextualised intervention strategies, Chapters 4 and 5 helped to increase the confidence in their potential acceptability by mapping them against explanatory models in the local context. Chapters 6 and 7 then allowed us to align these strategies against existing practises and thus further increased the confidence in the potential acceptability and feasibility of the selected strategies. Only after there was sufficient confidence in the potential suitability of the developing intervention to the contextual settings did we embark on implementing it in Chapters 8 to 10 and that allowed us to test the perceived suitability of the intervention and to refine it iteratively based on the experiences of delivering the intervention. Thus each step of the treatment development process played a crucial role in the development of CAP and doing away with any components that would probably weaken certain aspects of the treatment.

Table 11.2: Summary of the treatment development process for CAP

	Objective(s)	Methods	Summary results	Output
Understanding the available evidence and identifying gaps in the evidence				
Step 1	To identify evidence based psychosocial intervention strategies.	Review of published literature (n=18)	BI based on a range of strategies, including the most commonly used MI, is effective in reducing alcohol consumption in AUD. Other interventions based on cognitive and/or behavioural principles were also effective in reducing alcohol consumption in AUD. There is some evidence supporting interventions for AUD being effective in LMIC, when delivered in primary care, and when delivered by NSHW.	A list of effective psychosocial treatments for AUD generalisable to the PREMIUM programmes settings.
Step 2	To identify contextually appropriate practices for AUD	Review of the published (n=6) and grey literature (n=2)	A range of contextually relevant psychosocial treatment strategies were identified e.g. psycho-education, support groups, relapse prevention, social skills training, family psycho-education, and family counselling. There was contextually relevant evidence to support personalised feedback and MI, strategies that were identified in the international review.	A list of contextually relevant psychosocial treatment strategies
Defining the treatment				
Step 3	To describe the explanatory models	Review of the published (n=11) and grey literature	Psychological causes, socio-cultural causes, and functional use of alcohol were primarily perceived to be the	A description of explanatory models and

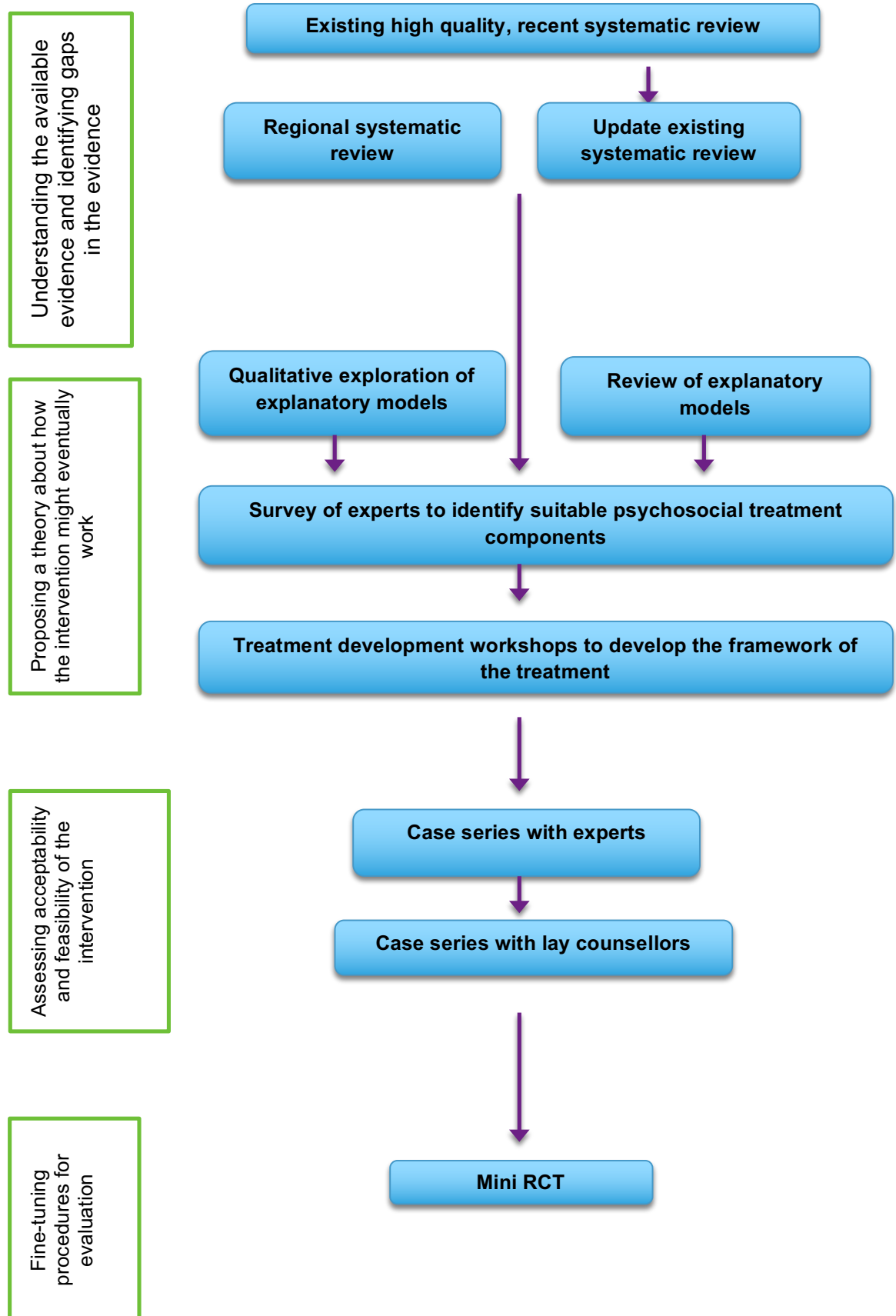
	Objective(s)	Methods	Summary results	Output
	of AUD in South Asia.	(n=1)	causes of drinking and drinking problems. There was general lack of understanding about the biomedical perspectives of AUD and the help available; and poor access to care for the small numbers that wanted to help.	help seeking behaviours of patients with AUD in South Asia.
Step 4	To explore the explanatory models of, define self-help and coping strategies used by, describe forms of psychological and other help sought by, and explore and define treatment expectations and desired outcomes of patients with AUD and their family caregivers (Nadkarni et al., 2013).	In depth interviews with men with AUD (n=29), SOs (n=10) and healthcare providers (n=33).	AUDs were seen to be associated with psychosocial stress, peer influences, availability of disposable income and drinking for pleasure. They are perceived to result in a range of adverse impacts on social life, family life, personal health and family finances. Various coping strategies were used e.g. avoidance, substitution, and distraction. Reduction or cessation in drinking, improved family relationships, improved wellbeing and better occupational functioning were the most desired treatment outcomes.	A list of psychosocial strategies being used by formal and non formal practitioners in India, and coping strategies used by and desired outcomes of patients with AUD and their family members.

	Objective(s)	Methods	Summary results	Output
Step 5	To identify psychosocial strategies that would be most feasible and safe for delivery by lay counsellors and acceptable by patients in the Indian context	Cross sectional survey with mental health professionals (n=15) and NSHW (n=43)	Personalised feedback, MI, psychoeducation, supportive counselling, cognitive restructuring, problem solving, enlisting social support, support groups, vocational counselling, relapse prevention, social skills training, family psycho-education, family counselling, relaxation, geographical cure, and physical exercise were perceived to be feasible and safe for delivery by lay counsellors and acceptable by patients in the Indian context. Religious and spiritual practises, addressing unconscious mechanisms, addressing interpersonal issues with one's partner, focus on past experiences and relationships, and music therapy were excluded at this stage as they were not deemed to acceptable/feasible/safe to be delivered by NSHW.	A list of evidence based and/or contextualised psychosocial strategies that would be acceptable, feasible and safe for delivery by NSHW to patients in the Indian context
Step 6	To form a coherent psychosocial treatment using the strategies identified in the previous steps and understand the barriers to delivering	Treatment development workshops with mental health professionals (n=30)	New strategies that were added included 'family engagement', 'treatment adherence', 'dealing with drinking triggers', 'referral to specialists', 'positive leisure activities', and 'healthy eating and sleeping routine'. Strategies that were removed included cognitive re-structuring, vocational counselling, support groups, physical exercise and geographical cure. Retained strategies were MI, psycho-	A list of psychosocial intervention strategies that were perceived to be mutually complementary and were arranged into a coherent treatment to be delivered over four

	Objective(s)	Methods	Summary results	Output
	a psychosocial treatment for harmful drinking by lay counsellors in primary care		education, personalised feedback, problem solving, relapse prevention, supportive counselling, enlisting social supports, relaxation, and social skills training	sessions.
Assessing acceptability and feasibility of the intervention				
Step 7	To describe the processes in and challenges to acquiring competencies in delivering MI for a clinical team comprising mental health practitioners	Treatment cohort with men with AUD (n=36)	Counselling Relationship (CR) manual and psycho-educational booklets with extensive pictorial content were developed. Modules on problem solving skills, drink refusal skills, handling difficult emotions, handling drinking urges, and relapse prevention were added to the developing manual.	The first draft of the CAP manual.
Step 8	To test the delivery of CAP by lay counsellors and to	Treatment cohort with male harmful drinkers (n=145)	CAP was converted from a session based one into a phasic intervention. CAP evolved into an intervention that gave the harmful drinker the choice of abstinence or	A contextually adapted treatment for harmful drinking with preliminary

	Objective(s)	Methods	Summary results	Output
	use the data collected during that process to further refine the CAP manual to enhance its acceptability and feasibility		controlled drinking as treatment goals. The intervention delivery was changed from being predominantly PHC based to delivery in the community if that was more convenient for the patient. The intervention also went from taking a stance that SOs should be assertively recruited in the intervention process to a more pragmatic approach of recruiting SOs only if they aided the therapeutic process. There was preliminary evidence to suggest that CAP led to reduction in the psychosocial impact of drinking.	evidence of impact.
Fine-tuning procedures for evaluation				
Step 9	To evaluate the preliminary impact of CAP and fine-tune the procedures for the eventual definitive RCT.	Pilot RCT with male harmful/dependent drinkers (n=53)	Compared to EUC, CAP had statistically non significant lower mean Alcohol Use Disorders Identification Test (AUDIT) score and mean alcohol consumed, greater mean reduction in the AUDIT score, higher odds of being abstinent, and less severe impact of their drinking.	Preliminary evidence of effectiveness of the CAP intervention, and data about process indicators needed to inform the definitive RCT procedures.

Figure 11.2: Framework for developing culturally and contextually adapted psychosocial intervention for harmful drinking



11.2.2 *Mapping the PREMIUM framework with other existing frameworks for cultural adaptation/development of psychosocial interventions*

Extensive evidence demonstrates that interventions developed using a variety of models to guide contextual adaptations are effective in a diverse range of health fields including asthma, diabetes, HIV/AIDS, nutrition, and exercise (Bailey et al., 2009; Darbes et al., 2008; Glazier et al., 2006; Mier et al., 2009). However, although there is a general consensus that effective public health interventions should pay due attention to the context in which the interventions will be delivered (Resnicow et al., 1998), in the field of mental health there continues to be a lively debate around issues such as when such adaptations are justified, the process of adaptation and the effectiveness of such contextually adapted interventions. One such un-answered question is related to the effectiveness of such adapted interventions. It is generally accepted that culturally adapted interventions are more effective than usual care or other control conditions. However culturally adapted psychosocial interventions have not been compared directly with the original interventions from which they are derived and hence we cannot be certain that cultural adaptations add any significant efficacy to the original intervention.

It has been proposed that the development of contextually appropriate interventions could take one of four treatment development approaches (Barrera and Castro, 2006) (a) a contextual adaptation of existing evidence-based interventions; (b) a sequential research-driven process beginning with exploration of the burden of disease followed by intervention development, testing and dissemination; (c) a top down approach in which experts provide the theory-based framework for the intervention and community members build in the contextually appropriate components; and (d) community members create the intervention which is then tested by researchers. The PREMIUM treatment development framework described above is a hybrid of these discrete approaches, taking a little bit from all, except the last, of these approaches. In doing so, this framework finds a middle ground between an universal approach (an intervention's content does not need any adaptations and applies to everyone regardless of context) and a context-specific approach (emphasis placed on the complex interplay between contextual uniqueness and content of

psychosocial interventions). Thus it fits in with Bernal's definition of a cultural adaptation as "the systematic modification of an evidence-based treatment to consider language, culture, and context in such a way that it is compatible with the client's cultural patterns, meanings, and values" (Bernal et al., 2009).

Over the years several models have been proposed to guide contextual adaptations and despite being developed independently they appear to have several convergence points (Barrera and Castro, 2006; Kumpfer et al., 2008; McKleroy et al., 2006; Wingood and DiClemente, 2008). One defining feature of these models is that they integrate existing theory and procedures ("top-down" elements), with input from contextually relevant stakeholder groups ("bottom-up" elements) to arrive at an adapted version that can then be rigorously evaluated. One such model defines a sequential model with four stages consisting of (a) information gathering, (b) preliminary adaptation design, (c) preliminary adaptation tests, and (d) adaptation refinement (Barrera and Castro, 2006) and this framework has similarities with the PREMIUM framework. Contextual adaptations of interventions for substance use disorders are limited. The evidence that exists is primarily of adaptations of interventions for ethnic minority groups. Research on such adaptations supports the effectiveness of contextually adapted versions of a prevention intervention aimed at delaying the onset of smoking, two programmes for preventing substance use among Black youth, MET for Black substance users, and an intervention to reduce HIV risk behaviours in ethnic minority males misusing substances. (Botvin et al., 1989; Brody et al., 2006; Calsyn et al., 2013; Longshore and Grills, 2000; Spoth et al., 2003).

To summarise, there are considerable similarities between these various independently developed models, amongst themselves (Barrera and Castro, 2006; Kumpfer et al., 2008; McKleroy et al., 2006; Wingood and DiClemente, 2008), and also with the PREMIUM framework. Some of the similarities include a) use of participatory research, b) use of mixed methods research, c) development of preliminary versions of the intervention, and d) pilot research (Castro et al., 2010).

11.2.3 *Major lessons learnt*

An overarching lesson learnt from comparing the PREMIUM framework with other frameworks used to develop/adapt complex interventions is the overlap in the processes/procedures followed by these frameworks. Such similarities, despite the different sources from which these frameworks are developed, in themselves enhance the confidence in the validity of the PREMIUM framework. Furthermore, the similarities also point towards the universality of certain core processes that go into the development of a contextually appropriate psychosocial intervention. These include triangulation of data from various sources, the use of the existing evidence base and supplementing it with new research, involvement of a range of stakeholders through participatory research, and development of the final intervention through iterative revisions of the preliminary intervention informed by data from various sources.

The other major lesson learnt about the treatment development process is from its output, the CAP intervention. The final CAP intervention developed from the systematic assembling of evidence based psychosocial strategies did not lead to 'deep' adaptations to the core components but 'surface' adaptations intended to enhance engagement and retention of the target group. This reinforces the universality of the various psychosocial intervention strategies and their applicability beyond the cultural groups for which they were originally developed, if suitable adaptations are made to increase access to the core strategies for the target group. More specifically for CAP, we learnt that the core theoretical understanding of the mechanism of maintenance of unhealthy drinking behaviours is applicable across contextual settings and hence the psychosocial intervention strategies derived from it are therefore also applicable across contexts. This also has implications for the future use of the PREMIUM framework and other similar treatment development/adaptation frameworks. If there is adequate confidence and/or evidence about the universal applicability of the theoretical understanding of the factors which lead to and maintain psychological problems then it would be possible to reduce the time spent on the treatment development process by compressing and/or skipping one or more steps of the treatment development process.

11.3 Limitations and strengths

In this section I will discuss the strengths and limitations within the various steps of the treatment development process. The limitations and strengths are related

to the overall intervention development process or to discrete steps of the process. The limitations and counter-arguments are discussed first, followed by the strengths.

In all the literature reviews conducted as a part of the treatment development process (Chapters 2, 3 and 4) papers were included only if they were published in English language journals. This is a particular limitation for the literature reviews of interventions for AUD in India (Chapter 3) and literature review of explanatory models of AUD in South Asia (Chapter 4). However, this may not be a significant limitation as most peer-reviewed public health and social sciences publications from South Asia are in English. Another limitation was related to the literature review of interventions for harmful drinking in India (Chapter 3) in which the inclusion criteria were relaxed to allow inclusion of study designs other than RCTs. Although these other study designs are lower down in the hierarchy of evidence, the idea was to focus more on the generalisability of the evidence rather than the robustness of the study design. Having too-strict criteria about study design would have ensured that we would not have any contextually relevant studies to inform the treatment development.

It is important to remember that although the treatment being developed by PREMIUM was for harmful drinking, the studies included in the reviews were those that tested interventions for harmful drinking alone as well as those for harmful and dependent drinking. The reason behind this was that in the AUD literature there are studies that test interventions for purely hazardous and purely dependent drinking, but studies of interventions for harmful drinking usually include dependent drinkers. However, this approach of including studies with a mix of harmful and dependent drinkers does not appear to be a major limitation as there is no reason to believe that psychosocial strategies for dependent drinkers are significantly different from those for harmful drinkers in terms of their mechanism of action.

To identify harmful drinkers in the project the cut off score for harmful drinking on the AUDIT was reduced from 16 (as recommended by the WHO) to 12. It could be argued that this would lead to inclusion of hazardous drinkers in the target group, thus biasing our findings. The WHO does allow for changes in the cut off scores on the AUDIT based on culture and drinking patterns. Although the ICD and DSM provide similar criteria for the identification of AUD, it is

unlikely that all cultures will have a similar threshold for identifying AUD, as prevailing norms in the society influences cultural views of substance use disorders (Gureje et al., 1996). Hence studies in different countries have used differing cut off scores for harmful/dependent drinking. The following cut off scores have been used to identify harmful drinkers in various cultures: 9 in Nigeria (Adewuya, 2005; Olisah et al., 2009), 8 in a Chinese population (Tsai et al., 2005), 9 in Nepalese population (Pradhan et al., 2012), and 10 for Tibetans (Guo et al., 2008). This indicates that the cut off score for harmful drinking recommended by the WHO are higher than what is appropriate and useful for LMIC settings; and our decision to reduce the cut off score is consistent with such precedents. As this decision was based on precedents from other countries and not from direct research from India, it was decided to be conservative in the reduction in the cut off score and hence a drastic reduction was not made, like in the other countries. There is not enough research about this issue in India and the cut off scores recommended by the WHO have generally been accepted at face value. However, our anecdotal experiences in the PREMIUM and a subsequent project developing an intervention for dependent drinkers indicates that men in India develop alcohol related problems at AUDIT scores lower than those recommended by the WHO. One could speculate that this could be because of the pattern of drinking in India that is predominantly characterised by drinking of spirits and drinking of large amounts of alcohol within short periods of time. Hence, further empirical research examining appropriate AUDIT cut off scores in India is warranted.

There were also certain participant level limitations across the various steps of the treatment development process. In the survey of local mental health experts and NSHW (Chapter 6) the response rate from the former was poor (58%) and this might have biased the findings, as the more experienced (and busier) clinicians would be more likely not to respond. However, it is possible that this limitation might have been offset to some extent by the involvement of local mental health experts in the treatment development workshops. Furthermore, in the survey a non-random sample was selected and thus the opinions of the sample with regard to perceived effectiveness, acceptability, feasibility, and safety might not be generalisable. The sampling strategy, along with the use of cut off scores for selection for which there is no precedent makes the whole process appear arbitrary. One could argue the possibility that these

psychosocial interventions were excluded at this stage because of the non representativeness of the sample making the judgement rather than the psychosocial strategies being truly poor fits for the contextual setting. However, by examining the results through the clinical lens it is not difficult to understand why psychosocial strategies like religious and spiritual practises, addressing unconscious mechanisms, addressing interpersonal issues with one's partner, focus on past experiences and relationships, and music therapy had to be excluded. All these strategies are ones that would require a substantive level of training and expertise to deliver; both factors making them unsuitable for delivery by NSHW. Finally, it is important to note that although these strategies were excluded at this stage there was always a possibility for these (or other) psychosocial strategies to be reintroduced in the developing treatment at the treatment development workshops (Chapter 7). Thus, the treatment development process did not rely on a single methodology and the multiple steps allowed for in-built checks and balances. A similar critique of the treatment development process would be that the participants were non-representative and the process inadequate as it was not empirical. Although this is a potentially valid argument one needs to keep in mind that the eventual validation of the steps in this treatment development process lies in the empirical evaluation of the CAP in the case series, pilot RCT and definitive RCT (not a part of my thesis). The results of the RCT demonstrate the effectiveness of CAP and this in turn indirectly validates the process that led to the development of CAP (Nadkarni et al., 2016). In the literature review of global evidence for interventions for AUD (Chapter 2) and the survey of mental health experts and NSHW (Chapter 6) scoring systems were devised to introduce an objective methodology for selection of relevant psychosocial strategies. These scoring systems were devised specifically for this project and did not have any precedent or evidence base. They do have face validity and appear to measure what they are supposed to measure. However, they are limited by the lack of empirical testing to test their validity and also the lack of weighting based on who was rating the strategies e.g. mental health professionals vs NSHW.

There were high refusal rates (for screening as well as participation) and dropout from treatment in both the case series and pilot RCT. However, this is not inconsistent with other studies of screening for AUD in primary care where a high percentage of patients who screen positive refuse further participation

(Anderson, 1993; Beich et al., 2003). One can imagine the reason for such high refusal rates being the fact that the patients who get screened are the ones who attend primary care for their physical health problems and don't consider their drinking as problematic. But such high refusal rates also mean that the representativeness of patients who participated in the studies needs to be considered. One way of examining this is through the differences between consenters and non-consenters and in the pilot RCT we did not find any significant differences between the two, although the sample size was underpowered to examine this definitively. An alternative method of recruitment could have been patients identifying themselves and actively seeking help after the programme was advertised in primary care. However, this would lead to a selection bias by recruitment of patients who are already motivated to change their drinking behaviour. Thus, although opportunistic screening and recruitment has limitations, it appears to be more representative of real world clinical practise. Drop out from treatment for AUD is not unusual and 10% to 30% of individuals with substance use disorders drop out of treatment in clinical settings (McKellar et al., 2006). There are several reasons for drop out from treatment and these include patient specific (e.g. younger age, lesser education, unemployment), treatment specific (e.g. therapeutic alliance) (McKellar et al., 2006), and disorder specific ones (e.g. lower severity of the alcohol problems which in turn may be associated with lower motivation for treatment) (Rees et al., 1984; Ryan et al., 1995). Except for employment status in the case series there were no significant differences between treatment completers and dropouts in the case series or pilot RCT. One possible explanation could be that the employed patients in our study settings are daily-wage workers and taking time out for attending sessions without losing a day's wages is not possible, thus leading to drop out from treatment. To summarise, consistent with clinical and research findings we also observed high refusal rates and drop out rates. The latter made us iteratively develop better strategies to improve treatment retention e.g. reminder SMS to participants a day before the scheduled therapy session. Looking forward, the high refusal and drop out rates have major implications for the scalability of CAP. Effectiveness, acceptability and feasibility are only three of many factors necessary for a successful scale up of a programme. Hence, although a scaled up CAP would address the supply side requirements, a parallel reduction in demand side

barriers will be essential to ensure adequate coverage. Although the treatment development process ensured that CAP was geared towards eventual scalability (e.g. home delivery of the intervention), the development of comprehensive strategies to increase demand are beyond the scope of a treatment development and testing programme, and these will have to be developed, tested, and iteratively refined in implementation programmes. Some potential barriers to demand in LMICs include lack of knowledge about providers, low ability to assimilate health choices and negotiate access to appropriate providers, long and slow travel to health facilities, need for patient to miss work (and wages) to access services, and patients seeking treatment through providers that are inappropriate to deal with their health condition (Ensor and Cooper, 2004). Implementation programmes could seek to overcome such barriers through multiple strategies including providing information about when and from whom to seek treatment, stimulating demand through financial incentives to seek treatment, provision of cheap flexible transport, incentives to reduce cost of lost working time etc.

Another limitation is the one that affects most studies requiring the measurement of substance use viz under-reporting. The reasons for such under-reporting include the participant actually believing the information they report (self-deception), or 'faking good' to conform to socially acceptable values, avoid criticism, or gain social approval (Huang et al., 1998; King and Bruner, 2000). Alternatives to self-reported drinking could be biological indicators and reports of collateral informants. But there appears to be a good agreement between patient self reports and collateral informant reports; and liver function tests appear to be relatively insensitive to AUD (Babor et al., 2000). Thus, using biochemical tests and collateral informant reports to complement self-report measures would not have added further value. Furthermore, we believe that certain characteristics of our interview process improved the accuracy of the self-report of drinking. These include the rapport with the research worker, the assurance of confidentiality, the clarity of the instructions, the non-complexity and short duration of the outcome evaluation, and the interval reported on (Babor et al., 1987). Our research workers were intensively trained to communicate/implement the former and the outcome tools used were simple, short, and covered a short recall period.

The Q-CAP is an important part of the CAP as it is used to ensure quality of the intervention delivered as well as helps the development and maintenance of the competency of the counsellors. Hence, its psychometric properties need to be appropriately examined and reported in future studies. The reliability of the Q-CAP has been examined (Singla et al., 2014) but not in its entirety. The internal consistency using the ratings of the therapists as well as from lay counsellors across various stages of the case series and intraclass coefficients to assess inter-rater reliability between expert and lay therapist peer and self-ratings were estimated. However, the Q-CAP has not undergone any formal validity testing (as there is no Gold Standard) or test-retest reliability analyses. Some of these gaps in testing are due to practical limitations such as the unavailability of many therapy experts who can contribute to the psychometric testing process. However, there are plans to assess the validity of the Q-CAP using the data from the definitive RCT. In the meanwhile, we have assumed that the Q-CAP has a certain level of face validity as it has been derived from similar tools that have been used widely in the field of psychological treatment research.

A criticism of a contextually adapted intervention like CAP could be that its utility is overstated as it assumes that cultural groups are a homogenous entity, when in fact in a large country like India there is extensive heterogeneity subsumed within a single culture. One solution to this involves adapting the intervention to the needs of a smaller cultural sub group within the larger culture, but this serves a narrow agenda (Castro et al., 2010). An alternative would be to adapt CAP to have decision rules which can be used to tailor its delivery depending on the needs of particular cultural subgroups (Castro et al., 2010). The advantage of such an approach would be that the intervention would closely mirror individualized clinical practice. However, the concern is about the ability of NSHWs to demonstrate the clinical flexibility that would be required of such an intervention.

CAP is a brief treatment that can be delivered in up to four sessions. It could be argued that the intensity of the intervention is not suitable for a non-treatment seeking population i.e. identified by screening as done in PREMIUM, and that a brief intervention would be more suitable. However, people with AUD in India do not seek treatment for AUD for a host of reasons such as fear of

embarrassment to family, high costs of treatment, lack of time, lack of insight into drinking problems, belief that one can control one's own drinking without any external support etc. (Kumar, 2016). All of this means that by the time a person seeks help specifically for AUD he/she has already developed alcohol dependence, sometimes severe dependence (Chand et al., 2013). Within such a context, waiting for patients with AUD to seek help and delivering brief treatments only to such patients might be self defeating and futile. Hence it is important to screen for harmful drinking and to deliver a relatively intense intervention even in a non treatment seeking population and attempt to prevent progression to a more severe form of AUD. It is also important to remember that the phasic nature of CAP means that patients could receive as few as one session and as many as four sessions based on need. This means that a patient requiring one session effectively receives a brief intervention and is not forced into receiving a brief treatment when not indicated.

One could argue that the lengthy process of intervention development followed by PREMIUM is a major limitation in an environment where research funding for mental health is limited, and that time and resources should rather be spent on the evaluation of the intervention. However, the counter-argument is that a rigorous treatment development process ensures that scarce resources are not wasted on evaluating interventions that might not work for lack of adequate formative work. A rigorous treatment development process leads to an intervention that is better designed, easier to evaluate, more likely to be effective, and worth implementing.

Finally, a limitation of the training process adopted in PREMIUM is that duplication of this rigour while scaling up in a low resource setting is going to be near impossible because of lack of specialist resources and time. Future research on CAP would have to examine whether the same level of competencies could be achieved with shorter training periods consistent with other NSHW trainings in the public health sector in India.

Table 11.3 summarises the limitations of the treatment development process and the counter-arguments for each.

Table 11.3: The limitations of the PREMIUM treatment development process

Limitations	Mitigation/rationale
Limitations of the discrete steps	
Only English language papers were included in the systematic reviews.	Most peer-reviewed public health and social sciences publications, including those from South Asia and India, are in English.
Non-RCT study designs included in literature review of interventions for harmful drinking in India.	Focus was on the generalisability of the evidence rather than the robustness of the study design.
Some studies included the reviews were those that tested interventions for harmful and dependent drinking.	No reason to believe that psychosocial strategies for dependent drinkers are significantly different from those for harmful drinkers.
Cut off score for harmful drinking on the AUDIT was reduced to 12.	The WHO does allow for changes in the cut off scores on the AUDIT based on culture and drinking patterns. Reduced cut off scores have been used in other countries indicating that the cut off score for harmful drinking recommended by the WHO are higher than what is appropriate and useful for LMIC settings.
Low response rated in the survey of local mental health experts.	This limitation might have been offset to some extent by the involvement of local mental health experts in the treatment development workshops.

Limitations	Mitigation/rationale
High refusal rates and dropout from treatment in the case series and pilot RCT	Consistent with findings from other studies of screening and treatment of AUD. Steps were put in place to reduce the refusal and attrition in the definitive RCT.
Self-report measures of alcohol use lead to under reporting.	Alternatives to self-report do not add any further value. Appropriate implementations of factors, such as assurance of confidentiality, improve the accuracy of the self-report of drinking.
Limitations of the overall treatment development process	
Lengthy process of intervention development is inappropriate when funds for research are limited	Rigorous treatment development process ensures that scarce resources are not wasted on evaluating interventions that might not work for lack of adequate formative work.
Utility of an adapted intervention is limited to the cultural sub-group for which it is developed as cultural groups are a not a homogenous entity.	Adapting an intervention to the needs of a smaller cultural sub- group within the larger culture, only serves a narrow agenda and NSHWs will find a flexible intervention with decision rules challenging to implement.

Just as the treatment development process had limitations it also had several strengths. The biggest strength of the process followed to develop CAP is the systematic and well-documented steps informed by robust scientific principles. Furthermore, all the steps were informed by peer reviewed sources e.g. Medical Research Council (MRC) framework, and treatment development steps used by other published research. Besides this over-arching strength there are several other strengths within the various steps of the treatment development process.

A strength of the review of the international literature on interventions for harmful drinking (Chapter 2) was that only the highest quality of evidence (i.e. RCTs and systematic reviews) was considered for inclusion. Furthermore, for the review, the focus on generalisability criteria (evidence from LMIC, primary care settings, disadvantaged or minority populations as recipients of the intervention, and NSHW as delivery agents), in addition to effectiveness, while evaluating the evidence base was an important strength of the process contributing to its contextual appropriateness.

Another major strength of the treatment development process is the contribution of various stakeholders to the participatory research components during the various stages of treatment development. National and international experts in the field of mental health, addictions, and complex intervention development brought in a range of complementary strengths to the treatment development process. The experts were involved in helping to draw conclusions from the literature reviews, qualitative study of explanatory models (Chapter 5) and survey of local mental health experts and NSHW (Chapter 6), advising on the designs of the various components of the treatment development process, treatment development workshops (Chapter 7), training and supervising the therapists (Chapter 8), training and supervising of the lay counsellors, and writing of the manual. Local clinicians working with people with addictions, both specialist and non-specialist, were involved in the qualitative study of explanatory models, survey of local mental health experts and NSHW, and the treatment development workshops. Patients with harmful drinking and their family members were involved in the qualitative study of explanatory models, case series with therapists (Chapter 8) and lay counsellors (Chapter 9), and the pilot RCT (Chapter 10). Finally, NSHW were involved in the qualitative study of explanatory models, survey of local mental health experts and NSHW, case

series with therapists and lay counsellors, and the pilot RCT. So the treatment development process involved a range of stakeholders including academics, specialist clinicians, NSHW, patients, and family members who brought in the right mix of a global perspective and contextual reality. The use of standardised tools to collect quantitative data in the case series and pilot RCT was another important strength. However, only some of these tools have been validated in India (e.g. AUDIT) while others had not been validated but used in previous research in India e.g. Short Inventory of Problems (SIP).

There is a constant tension between the need to maintain rigorous fidelity to the original evidence based intervention and need for adaptations to enhance the acceptability and feasibility of delivery to a specific cultural group (Bernal and Scharró-del-Río, 2001; Castro et al., 2004; Elliott and Mihalic, 2004). Purists argue that for a theory based and structured intervention to be efficacious it has to be delivered with high fidelity to the original intervention procedures and that there should be no compromise with regard to that (Elliott and Mihalic, 2004). On the other hand, supporters of contextual adaptations are of the opinion that if there is an 'intervention-consumer mismatch' due to cultural differences or diversity of ecological conditions then adaptations are necessary (Castro et al., 2010). Castro et al. (2004) made a strong case for such adaptations by demonstrating such 'intervention-consumer mismatch' at three levels (a) group characteristics, (b) program delivery staff, and (c) administrative/community factors. Table 11.4 below illustrates such an 'intervention-consumer mismatch' necessitating the cultural adaptation in the development of the CAP intervention.

Some of the other strengths of the procedures include those related to the recruitment, training, and supervision of the lay counsellors. Maintaining the quality of the intervention delivered was one of the primary goals of the PREMIUM programme. One of the important components of this was the phased acquisition of competencies within the team. So, the first step was the training and supervised practise by the therapists who then went on to become supervisors. Only when they achieved appropriate competencies were the lay counsellors trained. The selection of the lay counsellors was a rigorous process that involved pre-training evaluation of existing soft skills, acquisition of knowledge, post-training assessment of skills, supervised practise, and

competency evaluation before final selection. Another strength of the programme is the use of rigorous supervision procedures that had one eye on future scale-up. Use of audio recorded sessions for supervision is easily replicable as the ubiquitous cheap smart phone can be used to record therapy sessions. More importantly, the demonstration of good convergence of therapy quality rating scores between peers and expert supervisors provides a model of supervision that can be scaled up as it does away with the need for an expert supervisor.

Finally, one of the greatest strength of this treatment development process is the participation of a range of stakeholders and the triangulation of data collected using a range of methods from a variety of sources. This particularly enhances the contextual and cultural appropriateness of the CAP intervention and increases its chances of being a cost effective intervention to be delivered by NSW for harmful drinking in primary care.

Table 11.4: Sources of ‘intervention-consumer mismatch’ (Informed by Castro et al., 2010)

Source of mismatch	Original validation group(s)	Setting for PREMIUM	Actual or potential mismatch effect
Group characteristics			
Language	English	Konkani, Marathi, Hindi	Consumer inability to understand content
Ethnicity	White	Asian	Differences in beliefs, values and/or norms
Socioeconomic status	Upper and middle class	Lower middle and lower class	Limited social resources and culturally different life experiences
Urban-rural context	Urban	Peri-urban and rural	Logistical and environmental barriers affecting access to services
Program delivery staff			
Type of staff	Specialists	Lay health workers	Lesser or different delivery skills and professional experience
Administrative/community factors			
Community readiness	Moderate readiness	Low readiness	Absence of infrastructure and organisation to address alcohol use disorders, especially of the non-dependent variety.

11.4 The next step and implications

11.4.1 *The CAP intervention*

The definitive RCT to evaluate the cost effectiveness of CAP has recently concluded in Goa. In the parallel group RCT, adult male primary care attendees were screened with the AUDIT in 10 Primary Health Centres/Community Health Centres (PHC/CHC) and consenting eligible patients (AUDIT score 12-19) were randomly allocated in a 1:1 ratio to receive either CAP plus enhanced usual care or enhanced usual care (EUC) (n=377). Lay counsellors delivered CAP to the 188 participants randomised to the CAP condition. Session 1 was delivered to all these participants. Session 2 was delivered to 72.9% participants, session 3 to 46.3% participants, and session 4 to 17.6% participants. 30.3% participants dropped out (Mean number of sessions 1.1), and the rest completed treatment (Mean number of sessions 2.8). Primary outcomes (Time Line Follow Back [TLFB], SIP, and AUDIT) measurement was conducted at 3 months (90% follow up) post enrolment. 135 men with alcohol dependence were also randomised to CAP plus EUC or EUC. However, this was done for a secondary analysis that was not powered to test the effectiveness hypothesis in this particular sub group of AUD.

Besides cost effectiveness, the RCT will also allow us to examine some of the proposed mechanisms through which the CAP intervention works. A secondary analysis of the data will be conducted to determine whether treatment completion/treatment dosage predicts clinical outcomes and whether therapy quality predicts treatment mediators and clinical outcomes. Linear regression will be used to examine the relationship between Q-CAP (Quality of CAP) and TLFB; and to explore whether this relationship is mediated by patients' change talk (mention and discussion of his desire, ability, reason, need and commitment to change drinking behaviour).

If the CAP intervention is demonstrated to be cost effective then there are several implications for future research, clinical practice and health policy. To start with, the CAP intervention would have to be tested using RCTs in other LMICs, and also other contexts within India. The question that needs answering is whether an intervention developed in one low resource setting is effective in another or whether, despite common contextual strands, all low resource

settings are not equal and have fundamental differences that cannot be transcended without further context-specific adaptations. Additionally, would these further adaptations be surface adaptations to enhance delivery or deeper adaptations to the core content of the intervention? These are questions that can only be answered in further research on the CAP intervention in other contextual settings. None of these would be possible if the CAP intervention is not widely disseminated and freely available to anyone who wants to use, test or adapt it. Consistent with Sangath's open access philosophy the CAP manual and related material are freely available on its website (<http://sangath.com/manuals.php>). Taking this one step further we are currently in the process of digitising the manual in collaboration with NextGenU (<http://www.nextgenu.org/>). Once it goes live, anyone across the world wishing to be trained in the CAP intervention will be able to access the appropriate training materials which include text, lectures, and demo videos. The next step is to create a rigorous accreditation process and creation of an online community of practitioners that can support practitioners across the world through peer group supervision.

NSHWs are conceptualised to lie on a spectrum with the 'natural helper' (unpaid community members) at one end and the 'para-professional' (paid workers with minimal qualifications, trained and demonstrating acceptable levels of standardised competencies) at the other (Eng et al., 1997). Although the CAP intervention has been developed for and tested in lay counsellors (people with no health professional background but trained and supervised to deliver frontline psychosocial interventions) there is no reason to believe that it would not be suitable for delivery by NSHW across the spectrum described by Eng et al (1997), especially other non specialist health professionals e.g. peers, GPs and nurses. In fact, the latter would increase the coverage of treatments for AUD through the use of manpower already existing in the health system rather than creating an entirely new cadre of lay counsellors. However, this would come with its own set of challenges for already over-burdened health workers, the biggest being the time required to deliver an intervention which would, at the very least, take 30 minutes, even if the patient required a single session.

An intervention like CAP which is designed to overcome some of the traditional challenges to scaling up in low resource settings should be particularly appealing to policy makers. Although harmful drinking has a proportionately greater impact than alcohol dependence (Rehm et al., 2003) policy-makers have focused primarily on the latter (Benegal et al., 2009). This is especially evident in LMICs where health systems for treatment of AUD place a disproportionate emphasis on tertiary care based in rehabilitation centres, specialist addiction clinics, and psychiatric hospitals (Benegal, 2005; Parry, 2005; Perngparn et al., 2008), many of which are expensive, inequitably distributed, and geographically inaccessible. Hence, inadequate identification, under-treatment, and lack of contextually appropriate evidence based interventions for harmful drinking are the norm for AUD management in low resource settings like India. Besides policy maker apathy, there are several other reasons for this existing norm, including individual level factors (e.g. stigma, shame, doubting the need for treatment, non-recognition of the drinking behaviour as problematic by the drinker) as well as structural factors (e.g. inadequate or inaccessible services) (Saunders et al., 2006; Shin et al., 2012). In low resource settings structural factors such as inadequate health services, and practical barriers to accessing health care such as distance, influence help seeking more than in better resourced settings (Munro et al., 2007; Wolfe, 2007). In such circumstances, where there are demand barriers (e.g. low demand for AUD treatment by drinkers) and supply barriers (e.g. human resource shortage), an intervention like CAP that innovates with regard to delivery agent, as well as the location of delivery, would help greatly in increasing access to healthcare for harmful drinking by overcoming the supply side barriers.

However, despite emerging evidence about the cost effectiveness of task sharing initiatives in mental healthcare, this is yet to translate into tangible policy-driven changes on the ground. In LMICs, most task sharing initiatives are driven by NGOs like Sangath (the implementing NGO for PREMIUM), with strong local level impact, but with limited potential for scaling-up in larger population groups, and such efforts are generally short lived as they are dependent on short term external donor funding. The sustainability of task sharing initiatives to reduce the treatment gap is going to be dependent on a)

political commitment, b) availability of financial resources, c) realignment and strengthening of health services to successfully embed task sharing initiatives, d) establishment of appropriate training and supervision frameworks, e) initiation of relevant regulatory frameworks, and f) garnering of support from multiple stakeholders with divergent agendas (such as professional bodies; ministries of health and finance; nongovernmental and community organizations; and local health structures) (Lehmann et al., 2009). Most importantly, for an intervention like CAP to be successfully scaled up there needs to be a reorientation of policymakers' thinking from the conventional to one that is oriented towards creative solutions and problem solving.

Finally, interventions like the CAP intervention, which are designed to be delivered by NSHW in primary care, are in the unique position of having the potential of a national scale up in India. There are several reasons for this, the foremost being the policy environment. There are precedents in India where cost effective NSHW programmes have been taken up by the Government of India and scaled up across the country. The Society for Education, Action and Research in Community Health (SEARCH) conducted a RCT in Gadchiroli, a rural district in Maharashtra, India, on home-based neonatal care (HBNC) in which village health workers were trained to make home visits and manage birth asphyxia, premature birth or low birth-weight, hypothermia, breast-feeding problems, in addition to diagnosing and treating neonatal sepsis. The trial conducted in 39 intervention and 47 control villages demonstrated that SEARCH's HBNC approach reduced neonatal and infant mortality by nearly 50% (Bang et al., 1999). The HBNC model developed by SEARCH was then scaled up across India by the Government of India using NSHWs called as ASHAs (Accredited Social Health Activists). Along with such precedents to guide policy there is a fertile environment for mental health systems development as India's new mental health policy (<http://www.mohfw.nic.in/index1.php?lang=1&level=2&sublinkid=4723&lid=2964>) recommends the integration of mental health specific NSHWs in primary care across India. This policy recommends the creation of a cadre of health-workers that could be placed in primary care and would deliver frontline mental healthcare. As CAP is designed to overcome the traditional barriers to access it

aligns itself well with these policy recommendations described above. As mentioned previously, PREMIUM has also developed an intervention for depression (HAP) and the same set of lay counsellors delivered CAP and HAP in the RCT. If both HAP and CAP are found to be effective then it would demonstrate that a NSHW could be trained to be flexible enough to deliver psychosocial interventions for a range of mental health problems and this would further support the argument to create a new cadre of non-specialist workers dedicated to mental healthcare.

Although the CAP intervention has been designed keeping scalability in mind we need to keep in mind that scalability is influenced by a lot of factors beyond the cost effectiveness of the intervention, acceptability by the recipients, and feasibility of delivery by NSHW. Such factors include organisational policies, legislation and regulations, political support, levels of community engagement, leadership, demand for services, accountability systems, and social networks (Mangham and Hanson, 2010; Merzel and D’Afflitti, 2003; Bloem and Pee, 2010; Riley et al, 2007; Simmonds, 2008). So the eventual scalability of CAP would be depend on adequate allocation of human, financial and infrastructural resources, political commitment and policy support, attention to spatial (coverage, reach, availability and accessibility of services) (Bryce et al., 2004; Glasgow et al., 2006; Mangham and Hanson, 2010; Verma et al., 2010) and temporal (differential rate of change at each level of the system and the conditions that are required to initiate, sustain or alter change processes both within and between system levels) (Gunderson & Holling, 2002) dimensions of scaling up, and building up of demand and expectations for CAP among the targeted populations. Some of these factors were considered during the development of CAP e.g. delivery by NSHW, home delivery of the intervention, delivery through the primary care platform etc. Although conditions for sustainability and scale-up should be considered early on in the process of developing a complex intervention it is not possible to address all of these factors during the treatment development process. Hence, some factors will also have to be dealt with during initial implementation of the CAP in larger population groups and that will be the true test of the scalability of the intervention.

11.4.2 The PREMIUM framework

The PREMIUM framework is an addition to the other frameworks that are available for the development of psychosocial interventions. What is unique about the PREMIUM framework is that it takes the approach of dismantling evidence based psychosocial interventions into their component strategies and reassembling contextually appropriate strategies into a theory backed intervention package. This is unlike other frameworks which focus on adapting evidence based interventions in their entirety. Thus the PREMIUM framework informs the theory of treatment development by adding another approach to the existing frameworks. Furthermore, the experiences of the same treatment development process used for the development of the Healthy Activity Programme (HAP) (Chowdhary et al., 2015), the treatment for depression, in PREMIUM demonstrated that the treatment development framework transcends idiosyncrasies in the presentations of disorders. Some of the major lessons around HAP too were around strategies to increase treatment engagement, psycho-education, engagement of SO, phasic structure of the treatment, and home delivery to increase access. Thus the mirroring of the experiences in developing the two interventions and the final intervention packages indicate that these are not disorder specific and the same framework could be used to address the intervention development needs of other disorders in low resource settings. The framework is now available open access to anyone who wants to use it as the case studies for both the CAP and HAP interventions have been published in peer reviewed journals (Chowdhary et al., 2015; Nadkarni et al., 2015). Finally, a piece of work supplementary to the treatment development process was the evaluation of the contribution of each step of the process to the goals, and to assess the resources used for each of these steps (Vellakkal and Patel, 2015). These data were then triangulated to arrive at a parsimonious set of steps to guide others who might want to use the PREMIUM framework. This work concluded that although all the steps of the framework contributed to the development of the treatment, in the face of resource shortage, the steps can be limited to workshops with experts, case series and pilot RCT. This allows the user to apply the framework flexibly according to the availability of resources, another strength of the framework. At the same time one needs to be mindful that excluding certain steps like the qualitative interviews about explanatory

models removes one of the great strengths of the model i.e. the voices of local 'non experts'.

11.5 Conclusion

The PREMIUM treatment development process produced two tangible outputs. The CAP intervention is a potentially scalable contextually appropriate psychosocial intervention for harmful drinkers to be delivered by NSHWs in primary care. It is contextually appropriate because it has been designed using procedures that place a premium on contextual evidence, multiple stakeholder acceptability and feasibility for delivery by an easily available human resource; all tested using mixed methods and data triangulated from a variety of sources. It is potentially scalable because it is contextually appropriate and designed to be delivered by NSHW (consistent with recommendations made by the National Mental Health Policy in India) in primary care (the healthcare platform which has the greatest coverage in India). The other important output is a structured framework to guide the development of contextually appropriate psychosocial interventions for low resource settings. The CAP treatment development experience demonstrates how contextual factors can substantively influence the delivery format of a psychosocial intervention in low resource settings. On the other hand, the final structure and content of CAP highlights that despite explicit attention to contextually appropriate coping strategies and explanatory models, most strategies in the final treatment package appeared to have commonalities with other treatment packages used in high income country (HIC) contexts. The major adaptations to the intervention were aimed at increasing treatment engagement and adherence rather than to the core principles of the component strategies. Thus, following a systematic process of treatment development not only enhances the likelihood of acceptability and feasibility of a new psychosocial intervention but also demonstrates the universal applicability of some psychosocial strategies developed in HIC settings. If CAP is shown to be cost effective in the definitive RCT then it has the potential to reduce the treatment gap for AUD in LMICs. As the CAP intervention has been designed using a contextually sensitive treatment development process it is particularly suitable for increasing the penetration and coverage of treatment for AUD in low resource settings. This would be done through delivery by NSHW in primary

care to overcome the twin barriers to scale up viz specialist manpower shortage and contextual limitations of psychosocial interventions developed in the West. Finally, the PREMIUM treatment development framework is a systematic but flexible process that could be used across low resource settings to develop contextually appropriate psychosocial interventions for a range of disorders.

On a higher level, the original contribution of my work to theory and knowledge is related to the process and the outcome of the PREMIUM treatment development framework. The framework and the CAP intervention demonstrate that instead of spending scarce resources on developing new psychosocial therapies, it is possible to use existing evidence based psychosocial strategies to put together new interventions which are specifically tailored to meet the needs of a particular context. Furthermore, this new intervention can be made more accessible, acceptable, and feasible by applying contextual adaptations that do not adversely impact its potential effectiveness, as they don't alter the core characteristics of the component strategies.

Appendices

Appendix 1: List of key informants

Head, De-addiction Unit, NIMHANS, Bangalore

Additional Professor De-addiction Unit, NIMHANS, Bangalore

Director, TT Krishnamachari Institute of De-addiction, Chennai

Professor & Head of Department of Psychiatry, KEM hospital, Mumbai

Ex-Head of Department of Psychiatry, NIMHANS, Bangalore

Head of Department, Psychiatry, KEM Hospital, Pune

Associate Scientist, Alcohol Research Group, CA, USA

Senior Research & Technical Advisor, HealthNet TPO

Program Coordinator, Global Health Track, Mailman School of Public Health, Columbia University

Appendix 2: List of libraries visited for literature search

Library	Description	Types of Publications
Tata Institute of Social Sciences (TISS), Mumbai	Premier institute in social science research and training	<ul style="list-style-type: none"> • Journal articles • Theses
Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh	Premier institute of medical training and research	<ul style="list-style-type: none"> • Indian Psychology Abstracts & Reviews • Indian Psychological Review
National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore	Apex national institute of training and research in psychiatry	<ul style="list-style-type: none"> • De-addiction Quarterly • Theses (PhD Clinical Psychology, PhD Psychiatry, PhD Social Work, MPhil Psychology, MSc Nursing)
TT Krishnamachari Institute of De-addiction, Chennai	Leading institute for substance use treatment and research	<ul style="list-style-type: none"> • Manuals • Theses • Journal Articles

Library	Description	Types of Publications
Alcoholics Anonymous, Samara	Exhibition organized by Alcoholics Anonymous	<ul style="list-style-type: none"> • Manuals
Institute of Human Behaviour And Allied Sciences (IHBAS), New Delhi	Leading institute of mental health training and research	<ul style="list-style-type: none"> • Journals • Theses
National Medical Library, New Delhi	National medical library and information centre	<ul style="list-style-type: none"> • Journals • Reports
National Drug Dependence and Treatment Centre, New Delhi	Apex body of central government for treatment of addictions	<ul style="list-style-type: none"> • Journals • Reports

Appendix 3: Interview guides for qualitative study of explanatory models

In depth interview guide for patient with AUD

Introduction: *'I would like to start by asking you some questions about yourself. Can you tell me a little about yourself?'*

Perceptions of the illness

1. *Can you tell me about your problem? Can you tell me why you have come to _____(Name of health facility)?*
2. *What do you call this problem? (FOR THE REMAINING QUESTIONS USE THE NAME GIVEN INSTEAD OF THE WORD "PROBLEM")*
3. *How did the problem start? When did you first realise that you had a problem?*
4. *What according to you has caused the problem?*
5. *How has the problem affected your life? What has changed in your life after the problem started?*

Probe for impact in the following areas:

- Social functioning (Probe for any changes in relationships with friends/relatives; if so, in what way; for e.g. going out, meeting people, attending family functions, broken relationships).
- Family structure and relationships (Probe for any changes in role and position in family for e.g. not being a breadwinner any longer or not being able to look after the house).
- Occupational functioning (Probe for changes in performance at work/ loss of job (if any), the circumstances which caused this and the resulting hardships e.g. financial difficulties, or problems in relationships with colleagues).
- Health (Probe for any health problems following onset of illness).
- Economic conditions (Probe for changes in own/family finances and expenses)

For each of these, use general probes such as *how has the problem affected _____? What changes have there been regarding _____? Can you give me some examples of what you mean by _____? In what other way has it affected your life?*

6. *How has this problem affected the way you think/feel about/view yourself?* (Probe for feelings of shame, low self-esteem, low mood, irritability etc.)

7. *Does anyone know about your problem?* (Probe specifically for family reactions) If so, ask

a. *Who knows?*

b. *How have they behaved towards you after coming to know about your problem?* (Probe for ridicule, avoidance, neglect, changes in previous roles in family/ work/ friends)

c. *Why do you think they behaved this way? If not, ask Do you have any concerns about people knowing about your problem? If so, what are these?* (Probe for fear of others coming to know/ being ridiculed / ignored / feeling ashamed)

Desired outcomes

What changes would you like/expect in your life? What do you want from your treatment? (After allowing for sufficient open-ended exploration, probe specifically for whether changes are desired in areas of impact under theme 1)

Self-help/coping strategies

What do you do to manage/ cope with this problem? Can you describe what you do to make yourself feel better?

Probe after allowing for sufficient open-ended exploration: *Do you engage in religious/spiritual practices? Do you try to talk about it with someone? Do you keep yourself busy/ distract yourself by listening to music, reading or watching movies etc.?*

For each coping strategy, ask the following (cover ALL questions)

- *Can you describe this, with examples of how you did this and what happened?*
- *Under what circumstances do you try this?*
- *For how long have you tried this?*
- *How often (in a week) do you try this?*
- *Do you still try this?*
- *How has this helped you? Can you give examples of incidents where you believe that this has helped you? (After allowing for sufficient open-ended exploration, probe specifically for effect of coping strategy on areas of impact under theme 1).*

Probe, specifically for help seeking from family/ friends: *Is there anyone among your friends/family who you seek help from?*

If yes, ask

- *Who helps you?*
- *What help have they given to you?*
- *How has it helped you? Can you give examples of incidents where they have helped? (After allowing for sufficient open ended exploration, probe specifically for effect on areas of impact under theme 1)*

If no, ask

- *Why did you not seek help from friends/ family?*
- *Do you think they can help you? Who?*
- *What help do you think they can give you?*
- *How do you think this will help you? Can you give examples of incidents where they can help? (After allowing for sufficient open ended exploration, probe specifically for potential effect on areas of impact under theme 1)*

Help Seeking Behaviour

1. *When did you first seek help for this problem (how many months/years ago)?*
2. *What made you do this? (Probe: Did you perceive it as a problem that needs professional help? Who advised you? How did you learn about this?)*
3. *What help have you sought for this problem? Who did you seek help from? (Probe after allowing for sufficient open-ended exploration: psychiatrist, psychologist, general practitioner, Ayurveda, religious healer, home remedies etc.)*

For each treatment, ask the following (cover ALL questions)

- *What did [the person you saw] do to help you?*
- *Can you describe what happened in the meeting/session?*
- *For how long did you receive it (years/ months)?*
- *Is this continuing even now?*
- *How many sessions/ visits have you had in total?*
- *How often (in a week) did you get help?*
- *How many sessions did you receive in total?*
- *How long was each session?*
- *Where did you receive this treatment?*
- *Was your family involved? If so, who was involved and how were they involved?*
- *How has this treatment helped you? Can you give me some examples (After allowing for sufficient open ended exploration, probe specifically for effect in areas of impact under theme1 AND for ability to result in desired outcomes under theme 2)?*
- *How long (in months) did it take for you to get benefits?*

- *How long (in months) did this effect last?*
- 4. *Can you tell which of these treatments have helped you the most? Why do you feel this is better than the others? What ways did it help that the others did not? Would you recommend this treatment to others who have the same problem, and if so, why?*
- 5. *Have you experience any harm/ill effects from these treatments? (If yes, ask for details)*

Unmet needs and desired treatments

In what ways have each of the treatments you have received not helped you? (After allowing for sufficient open ended exploration, probe specifically for no/inadequate effect of each treatment on areas of impact in theme1 AND inability of treatment to result in desired outcomes in theme 2)

For each unmet need, ask the following, cover ALL questions

- *What treatment do you think will meet this need?*
- *What should this treatment/s consist of?*
- *What should happen in treatment sessions?*
- *Who should give this treatment?*
- *Where should you get this treatment/s?*
- *How often (in a month) should it/they be given?*
- *How long (months/years) should this treatment/s be given?*
- *Should others in the family be involved? Who? What should be their role? How can they help?*

Closing Questions

We have reached the end of the interview. Is there anything more you'd like to tell me that we have not already discussed? Do you have any questions for me about anything we discussed?

Thank you again for your time and for allowing me to talk to you.

In depth interview guide for SO of patient with AUD

Introduction: *'I would like to start by asking you some questions about yourself. Can you tell me a little about yourself?'*

Perceptions of the Illness

1. *Can you tell me about your _____ (relationship with patient of AUD) problem? Can you tell me why your _____ (relationship with patient of AUD) has come to _____ (Name of health facility)?*
2. *What do you call this problem? (FOR THE REMAINING QUESTIONS USE THE NAME GIVEN INSTEAD OF THE WORD "PROBLEM")*
3. *How did the problem start? When did you first realise that your _____ (relationship with patient of AUD) had a problem?*
4. *What according to you has caused the problem?*
5. *How has the problem affected your _____ (relationship with patient of AUD) life? What has changed in your _____ (relationship with patient of AUD) life after the problem started?*

Probe for impact in the following areas:

- Social functioning (Probe for any changes in relationships with friends/relatives; if so, in what way; for e.g. going out, meeting people, attending family functions, broken relationships).
- Family structure and relationships (Probe for any changes in role and position in family for e.g. not being a breadwinner any longer or not being able to look after the house).
- Occupational functioning (Probe for changes in performance at work/loss of job (if any), the circumstances which caused this and the resulting hardships e.g. financial difficulties, or problems in relationships with colleagues).
- Health (Probe for any health problems following onset of illness).

- Economic conditions (Probe for changes in own/family finances and expenses)

For each of these use general probes such as “*How has the problem affected _____? What changes have there been regarding _____? Can you give me some examples of what you mean by _____? In what other way has it affected your life?*”

6. *How has this problem affected the way your _____(relationship with patient of AUD) thinks/ feels about/ views himself?* (Probe for feelings of shame, low self-esteem, low mood, irritability etc.)

7. *Does anyone know about your _____(relationship with patient of AUD) problem?* (Probe specifically for family reactions) If so, ask

d. Who knows?

e. *How have they behaved towards your _____(relationship with patient of AUD) after coming to know about his problem?* (Probe for ridicule, avoidance, neglect, changes in previous roles in family/ work/ friends)

f. *Why do you think they behaved this way?* If not, ask *Do you have any concerns about people knowing about your _____(relationship with patient of AUD) problem? If so, what are these?* (Probe for fear of others coming to know/ being ridiculed / ignored / feeling ashamed)

Desired outcomes

What changes would you like/expect in your _____(relationship with patient of AUD) life? What do you want from your _____(relationship with patient of AUD) treatment? (After allowing for sufficient open-ended exploration, probe specifically for whether changes are desired in areas of impact under theme 1)

Self-help/coping strategies

What do you do to manage/cope with this problem? Can you describe what you do to make yourself feel better?

Probe after allowing for sufficient open-ended exploration: *Do you engage in religious/spiritual practices? Do you try to talk about it with someone? Do you keep yourself busy/ distract yourself by listening to music, reading or watching movies etc.?*

For each coping strategy, ask the following (cover ALL questions)

- *Can you describe this, with examples of how you did this and what happened?*
- *Under what circumstances do you try this?*
- *For how long have you tried this?*
- *How often (in a week) do you try this?*
- *Do you still try this?*
- *How has this helped you? Can you give examples of incidents where you believe that this has helped you? (After allowing for sufficient open-ended exploration, probe specifically for effect of coping strategy on areas of impact under theme 1).*

Probe, specifically for help seeking from family/ friends: *Is there anyone among your friends/family who you seek help from?*

If yes, ask

- *Who helps you?*
- *What help have they given to you?*
- *How has it helped you? Can you give examples of incidents where they have helped? (After allowing for sufficient open ended exploration, probe specifically for effect on areas of impact under theme 1)*

If no, ask

- *Why did you not seek help from friends/family?*

- *Do you think they can help you? Who?*
- *What help do you think they can give you?*
- *How do you think this will help you? Can you give examples of incidents where they can help? (After allowing for sufficient open ended exploration, probe specifically for potential effect on areas of impact under theme 1)*

Help Seeking Behaviour

1. *When did you first seek help for this problem (how many months/ years ago)?*
2. *What made you do this? (Probe: Did you perceive it as a problem that needs professional help? Who advised you? How did you learn about this?)*
3. *What help have you sought for this problem? Who did you seek help from? (Probe after allowing for sufficient open-ended exploration: psychiatrist, psychologist, general practitioner, Ayurveda, religious healer, home remedies etc.)*

For each treatment, ask the following (cover ALL questions)

- *What did [the person you saw] do to help you?*
- *Can you describe what happened in the meeting/session?*
- *For how long did you receive it (years/months)?*
- *Is this continuing even now?*
- *How many sessions/visits have you had in total?*
- *How often (in a week) did you get help?*
- *How many sessions did you receive in total?*
- *How long was each session?*
- *Where did you receive this treatment?*

- *Was your family involved? If so, who was involved and how were they involved?*
 - *How has this treatment helped your _____(relationship with patient of AUD)? Can you give me some examples (After allowing for sufficient open ended exploration, probe specifically for effect in areas of impact under theme1 AND for ability to result in desired outcomes under theme 2)?*
 - *How long (in months) did it take for your _____(relationship with patient of AUD) to get benefits?*
 - *How long (in months) did this effect last?*
6. *Can you tell which of these treatments have helped your _____(relationship with patient of AUD) the most? Why do you feel this is better than the others? What ways did it help that the others did not? Would you recommend this treatment to others who have the same problem, and if so, why?*
7. *Have your _____ (relationship with patient of AUD) experienced any harm/ill effects from these treatments? (If yes, ask for details)*

Unmet needs and desired treatments

In what ways have each of the treatments your _____(relationship with patient of AUD) has received not helped him? (After allowing for sufficient open ended exploration, probe specifically for no/inadequate effect of each treatment on areas of impact in theme 1 AND inability of treatment to result in desired outcomes in theme 2)

For each unmet need, ask the following, cover ALL questions

- *What treatment do you think will meet this need?*
- *What should this treatment/s consist of?*
- *What should happen in treatment sessions?*
- *Who should give this treatment?*

- *Where should you get this treatment/s?*
- *How often (in a month) should it/they be given?*
- *How long (months/ years) should this treatment/s be given?*
- *Should others in the family be involved? Who? What should be their role? How can they help?*

Closing Questions

We have reached the end of the interview. Is there anything more you'd like to tell me that we have not already discussed? Do you have any questions for me about anything we discussed?

Thank you again for your time and for allowing me to talk to you.

In depth interview guide for patient with healthcare provider

Background information

I would like to start by asking you some questions about the nature of your work.

- *What is the nature of your work?*
- *With what problems do people usually come to you /visit you to seek your help or advice?*
- *How many people do you see in a week? (Probe for each problem reported above, with more emphasis on AUD)*
- *How many hours in a week do you do this work?*
- *How long have you been providing this kind of help?*

Treatments provided by care provider

1. *What do you do to help people with _____ (Probe for each problem reported above, with more emphasis on AUD) (List treatments or techniques)?*

For each reported treatment probe:

- a. *What is the technique you use/ what is the name of the method you described?*
- b. *How is it provided?*
 - *How many times do the patients to come to meet you or visits/ sessions in total (on an average, considering a set of persons with illness) do you give for this treatment?*
 - *How long is each session/visit?*
 - *How often (in a week) do you have these sessions?*
 - *What is the format of delivery of the sessions? (Group, individual etc.)*
 - *Can you describe what happens in a typical session from start to finish? (Please note, if the treatment is provided in different phases/stages, then to describe a typical session in each phase/stage)*
- c. *Who delivers this treatment? (Probe: is it only by you or are others involved? What do they do? What is the role of each person involved?)*
- d. *To whom is the treatment delivered? (Probe: to the person with the illness/to groups of persons/families?)*
- e. *Where do you deliver this treatment? (Probe: clinic/residence or elsewhere)*
- f. *Why do you use this technique? How do you think this works? In what ways does it help people? Can you give me some examples (Probe for impact on areas commonly affected by the illness)*
- g. *Does it work for everyone or only for some people? (Probe: for example, does it work better for younger people?)*
- h. *How long (roughly, in months) do the effects of this treatment last?*
- i. *How long should this treatment be given (months/years)?*

- j. *Are there any harmful effects/negative consequences of this treatment? If so, what are they?*
 - k. *Does the treatment need to be adapted to particular populations/settings? (Probe: for example, are there some people who do not respond to the treatment as well as you would expect? Who are they? Do you modify the treatment for them? How?)*
 - l. *Do you involve the family in the treatment? If yes, how? What do you think is the role of the family? How does family involvement help?*
2. *Can you tell which of these treatments help the most? Why do you feel this is better than the others?*

Help seeking strategies of persons with illness

1. *In your opinion what help/ treatments do persons with _____ seek? (Probe for each problem reported above, with more emphasis on AUD related problems such as drinking, stress, tension etc.)*
2. *Who do they seek help from? (Probe: from psychiatrist, psychologist, general practitioner, Ayurveda, religious healer, home remedies etc.)*
3. *What is the kind of help/ treatments they receive? What do the people who provide treatment do to help him/her (what methods/ techniques do they use)?*
4. *[For each type of treatment reported] Does this treatment help them?*

If yes, how/why do you think this has helped? Can you give me some examples (Probe for impact of such treatments on areas commonly affected by the illness)?

If no, in what ways do you think it has not helped him? (Probe for lack of impact in areas commonly affected by the illness) Why do you think this is the case?
5. *Can you tell which of these treatments help the most? Why do you feel this is better than the others?*

Acceptability, feasibility of provision by Non Specialist Health Worker

For the treatments that you have mentioned above (probe for each)

1. *What do you think of a person without any background or qualifications in mental health, a non-professional, (after training) delivering this treatment?*
2. *What are the skills required by a non-specialist health worker to deliver this treatment? (Probe for technical skills specific to that therapy as well as generic skills such as communication, empathy and so on)*
3. *What are the educational qualifications needed for delivering this treatment?*
4. *What is the kind of training required (if any)? In what areas should the person be trained? By whom? How long should the training be?*
5. *What form/method of supervision does the person need? What areas should he/she be supervised on? By whom? How often? How will the supervision change over time?*
6. *What are the barriers you foresee with a non-specialist delivering the treatment? How do you think these can be overcome?*

Closing Questions

We have reached the end of the interview. Is there anything more you'd like to tell me that we have not already discussed? Do you have any questions for me about anything we discussed?

Thank you again for your time and for allowing me to talk to you.

Appendix 4: Questionnaires used in survey of mental health professionals and NSHWs

SURVEY OF MENTAL HEALTH PROFESSIONALS

Psychosocial Treatment Strategies Questionnaire

GOAL: The goal of the study is to see which psychosocial treatment strategies are **feasible, acceptable, effective** and **safe** when delivered to people with Alcohol Use Disorders (AUD) by Non Specialist Health Workers (NSHW). A NSHW is any person who has not had any formal training in mental health care. A typical example of NSHW for the purpose of this study would be a lay or community health worker in a public health program.

SOURCE: The list of psychosocial treatment strategies for AUD described here has been identified through extensive literature reviews of the international and local literature.

INSTRUCTIONS: Through this questionnaire, we ask you to rate each treatment strategy on various dimensions based on your knowledge and experience. There are four dimensions (defined below) for each treatment strategy.

- 1) Feasibility:** It is possible for NSHW, with appropriate training and supervision, to deliver this strategy to a person with the disorder.
- 2) Acceptability:** the person with the disorder easily receives the strategy as suitable within the Indian cultural context and circumstances.
- 3) Effectiveness:** The strategy brings about an observable change in the disorder, which is of expected direction and magnitude.
- 4) Risk of Harm:** There is a potential for harm or risk involved in an NSHW delivering this strategy to a person with this disorder.

For each of the above dimensions, you have to rate each treatment strategy on a scale of 1 to 5, where **1** denotes **Low probability** and **5** denotes **High probability**.

NOTE: For the '**Risk of Harm**' dimension, the scale remains the same but the **meaning of the rating changes**. Thus, the rating 1 for Risk of Harm dimension would mean low probability of harm and 5 would mean high probability of harm.

- Please click only on one box that corresponds to your rating of a given treatment strategy for each dimension. In case you want to change your first response, you can re-click on your response to uncheck it.
- Please note that the rating of each dimension is independent of your ratings of other dimensions.
- Please provide an answer for ALL the treatment strategies. Do not leave any dimension column blank.

Demographic Profile

Name:

Age: **Gender:**

Qualification(s): **Years of experience in mental health practice:**

E-mail: **Telephone No.:**

Organization Name, Designation and Address:

Area of expertise in psychosocial treatment: *(Check all that apply)*

- ☐ Cognitive Behaviour Therapy
- ☐ Behaviour Therapy
- ☐ Interpersonal Psychotherapy
- ☐ Mindfulness-Based Cognitive Therapy
- ☐ Psychoanalytic Psychotherapy
- ☐ Person-Centred Psychotherapy
- ☐ Rational Emotive Therapy

- ☐ Family Therapy
- ☐ Transactional Analysis
- ☐ Motivational Interviewing
- ☐ Any Other (Please specify): _____

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Psycho-education Providing information to help patients with AUD understand their symptoms, offer them hope and motivate them for treatment.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Personalised feedback	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Measuring a person's alcohol consumption and its related behaviours and giving feedback about this to the person.	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Motivational enhancement Strengthening a person's own motivation for and commitment to change by exploring and resolving the contradictory emotions about alcohol use.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Problem solving Generating a list of problems, and evaluating and choosing options designed to address these problems, thereby reducing the helplessness and	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
hopelessness associated with AUD.	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Supportive counselling Using a person's strengths and social supports to help them focus on coping with current issues.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Enlisting social support Employing important persons in one's social networks to encourage healthy behaviours and reduce alcohol use.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Social skills training Learning to use appropriate skills to handle	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
social situations and manage related emotions, and to handle interpersonal relationships and functioning in the workplace, thereby reducing alcohol use	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Vocational counselling Helping a person with AUD to choose appropriate career options.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Cognitive restructuring Learning to identify and question dysfunctional cognitions and cognitive processes with the aim of establishing more accurate or functional ones.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Geographical cure Shifting the person with AUD temporarily to a new location or to a location where there is no or limited access to alcohol.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Music therapy Using music in a skilled manner to help overcome physical, emotional, and social challenges associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Use of religious/spiritual practices Encouraging rituals or prayers that involve a	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
reverent petition made to god or other objects of worship.	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Relaxation Training of patients in methods of lowering their level of psycho- physiological arousal with the aim of reducing the physical and psychological features of anxiety associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Physical exercise Encouraging bodily activity that enhances or maintains physical fitness and overall health and wellness.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Focus on past experiences and relationships Providing insights into how AUD and associated difficulties relate to childhood experiences and the quality and nature of present and past relationships.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Addressing unconscious mechanisms Helping the person understand how hidden inner mental processes, for example dreams or the denial about past painful experiences are related to their AUD, thereby providing opportunities for change.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Family psycho-education	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 1

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Giving families information about AUD, helping them build social supports, and enhance problem solving, communication and coping skills.	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Family counselling Dealing with the family as a unit, addressing their unhelpful interaction patterns thereby resolving family conflicts associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Addressing interpersonal issues with one's partner Treatment of an adult couple primarily addressing the marital relationship (that is the	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
communication and interactional aspects of living together) with the goal of reducing alcohol use.	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Support groups Facilitating the meeting of groups of persons who share a common experience of AUD, in order to provide support to each other and information and advice on health and related problems.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Relapse prevention Training to anticipate and cope with high-risk situations with the aim of preventing relapse of AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

SURVEY OF NSHW

Psychosocial Treatment Strategies Questionnaire

GOAL: The goal of the study is to see which psychosocial treatment strategies are feasible, acceptable, effective and safe when delivered by Non Specialist Health Workers (NSHW) to people with Alcohol Use Disorders (AUD). A NSHW is any person who has not had any formal training in mental health care. A typical example of NSHW for the purpose of this study would be a lay or community health worker in a public health program.

SOURCE: The list of psychosocial treatment strategies for AUD described here has been identified through extensive literature reviews of the international and South Asian literature.

INSTRUCTIONS: Through this questionnaire, we ask you to rate each treatment strategy on various dimensions based on your knowledge and experience. There are four dimensions (defined below) for each treatment strategy.

- 5) **Feasibility:** It is possible for NSHW, with appropriate training and supervision, to deliver this strategy to a person with the disorder.
- 6) **Acceptability:** the person with the disorder easily receives the strategy as suitable within the Indian cultural context and circumstances.
- 7) **Effectiveness:** The strategy brings about an observable change in the disorder, which is of expected direction and magnitude.
- 8) **Risk of Harm:** There is a potential for harm or risk involved in an NSHW delivering this strategy to a person with this disorder.

For each of the above dimensions, you have to rate each treatment strategy on a scale of 1 to 5, where **1** denotes **Low probability** and **5** denotes **High probability**.

NOTE: For the '**Risk of Harm**' dimension, the scale remains the same but the **meaning of the rating changes**. Thus, the rating 1 for Risk of Harm dimension would mean low probability of harm and 5 would mean high probability of harm.

- **Please tick only on one box that corresponds to your rating of a given treatment strategy for each dimension.**
- **Please note that the rating of each dimension is independent of your ratings of other dimensions.**
- Please provide an answer for ALL the treatment strategies. Do not leave any dimension column blank.

Demographic Profile

Name:

Age: **Gender:**

Qualification(s):

E-mail: _____ **Telephone No.:** _____

Area of work:

Years of experience in mental health practice:

Organization Name, Designation and Address:

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Psycho-education Providing information to help patients with AUD understand their symptoms, offer them hope and motivate them for treatment.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Personalised feedback Measuring a person's alcohol consumption and its related behaviours and giving feedback about this to the person.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Motivational enhancement Strengthening a person's own motivation for and commitment to change by exploring and resolving the contradictory emotions about	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
alcohol use.	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Problem solving Generating a list of problems, and evaluating and choosing options designed to address these problems, thereby reducing the helplessness and hopelessness associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Supportive counselling Using a person's strengths and social supports to help them focus on coping with current issues.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Enlisting social support Employing important persons in one's social	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
networks to encourage healthy behaviours and reduce alcohol use.	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Social skills training Learning to use appropriate skills to handle social situations and manage related emotions, and to handle interpersonal relationships and functioning in the workplace, thereby reducing alcohol use	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Vocational counselling Helping a person with AUD to choose appropriate career options.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Cognitive restructuring Learning to identify and question dysfunctional cognitions and cognitive processes with the aim of establishing more accurate or functional ones.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Geographical cure Shifting the person with AUD temporarily to a new location or to a location where there is no or limited access to alcohol.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Music therapy Using music in a skilled manner to help overcome physical, emotional, and social challenges associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Use of religious/spiritual practices Encouraging rituals or prayers that involve a reverent petition made to god or other objects of worship.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Relaxation Training of patients in methods of lowering their level of psycho- physiological arousal with the aim of reducing the physical and psychological features of anxiety associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Physical exercise Encouraging bodily activity that enhances or	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
maintains physical fitness and overall health and wellness.	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Focus on past experiences and relationships Providing insights into how AUD and associated difficulties relate to childhood experiences and the quality and nature of present and past relationships.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Addressing unconscious mechanisms Helping the person understand how hidden inner mental processes, for example dreams or the denial about past painful experiences	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
are related to their AUD, thereby providing opportunities for change.	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5	<input type="checkbox"/> 5
Family psycho-education Giving families information about AUD, helping them build social supports, and enhance problem solving, communication and coping skills.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Family counselling Dealing with the family as a unit, addressing their unhelpful interaction patterns thereby resolving family conflicts associated with AUD.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Addressing interpersonal issues with one's partner	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 1 <input type="checkbox"/> 2

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
Treatment of an adult couple primarily addressing the marital relationship (that is the communication and interactional aspects of living together) with the goal of reducing alcohol use.	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Support groups Facilitating the meeting of groups of persons who share a common experience of AUD, in order to provide support to each other and information and advice on health and related problems.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
Relapse prevention Training to anticipate and cope with high-risk situations with the aim of preventing relapse	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3

Treatment strategy (Description)	Dimensions			
	Tick only on one box for each dimension			
	Acceptability Patient easily receives strategy as suitable within Indian cultural context	Feasibility Possible for NSHW with appropriate training and supervision to deliver	Effectiveness Strategy brings about an observable and expected change	Risk of harm Involves potential for harm if delivered by NSHW
of AUD.	<input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> 4 <input type="checkbox"/> 5

Appendix 5: Content analysis of existing manuals of psychosocial treatment for AUD

Criteria	Very Low (1)	Low (2)	Average (3)	High (4)	Very high (5)
To what extent is the manual directed for/suitable for use by a lay/community health worker?					
Reason:					
Engagement factors: To what extent does the manual address issues related to therapist engagement?					
Reason:					
Structure of sessions: To what extent does the manual provide a clear sessional outline and also the number and duration of sessions?					
Reason:					
Description of techniques: To what extent does the manual provide detailed description of psychosocial treatment techniques?					

Criteria	Very Low (1)	Low (2)	Average (3)	High (4)	Very high (5)
Reason:					
Language: To what extent is the language used in the manual appropriate for use by non-specialists in the Indian cultural context?					
Reason:					
Supporting material: To what extent does the manual include supporting material such as patient information materials, checklists etc.?					
Reason:					
Flexibility: To what extent does the manual provide options in treatment delivery methods thus allowing the therapist to be flexible in delivering the psychosocial treatment? (For example, for less literate patients or on the telephone)					
Reason:					

Criteria	Very Low (1)	Low (2)	Average (3)	High (4)	Very high (5)
Addressing challenges: To what extent does the manual address problems that may arise during treatment with solutions for these?					

Appendix 6: Alcohol Use Disorders Identification Test (AUDIT)

Introduction: Now I will ask you a few questions regarding your drinking in the last 3 months.

QA1. AUDIT1. How often do you have a drink containing alcohol?

- 0- Never ☐ [Skip to Qs 9-10]
- 1- Monthly or less ☐
- 2- Two to four times in a month ☐
- 3- Two to three times a week ☐
- 4- Four or more times a week ☐

QA2. AUDIT2. How many drinks do you have on a typical day when are you are drinking? (Note: 1 drink=10g). (Use table given to calculate Standard Drinks)

- 0- 1 or 2 drinks ☐
- 1- 3 or 4 drinks ☐
- 2- 5 or 6 drink ☐
- 3- 7 or 8 or 9 drinks ☐
- 4- 10 drinks or more ☐

QA3.AUDIT3. How often do you have 6 or more drinks (replace with equivalent amount from box below) on one occasion?

Note: 6 drinks is equal to
Regular Beer- 2 and ½ bottles
Strong Beer- 1 and ½ bottle
Spirits- 1 Quarter
Wine-1 bottle
Caju Feni-1 Quarter
Coconut Feni-1 and ½ Quarter
Urrack-2 Quarters
Pre Mixed Drinks- 6 bottles

- 0- Never ☐
- 1-Less than monthly ☐
- 2-Monthly ☐
- 3-Weekly ☐
- 4-Daily or almost daily ☐

Skip to Questions 9 and 10 if Total Score for Questions 2 and 3 = 0

QA4.AUDIT4. How often during the last three months have you found that you were not able to stop drinking once you started?

- 0- Never ☐
- 1-Less than monthly ☐
- 2-Monthly ☐
- 3-Weekly ☐

4-Daily or almost daily ☐

QA5. AUDIT5. How often during the last three months have you failed to do what was normally expected of you because of drinking?

- 0- Never ☐
- 1-Less than monthly ☐
- 2-Monthly ☐
- 3-Weekly ☐
- 4-Daily or almost daily ☐

QA6. AUDIT6. How often during the last three months have you needed a first drink in the morning to get yourself going after a heavy drinking session?

- 0- Never ☐
- 1- Less than monthly ☐
- 2- Monthly ☐
- 3- Weekly ☐
- 4- Daily or almost daily ☐

QA7 AUDIT7. How often during the last three months have you had a feeling of guilt or remorse after drinking?

- 0- Never ☐
- 1- Less than monthly ☐
- 2- Monthly ☐
- 3- Weekly ☐
- 4- Daily or almost daily ☐

QA8 AUDIT8. How often during the last three months have you been unable to remember what happened the night before because you had been drinking?

- 0- Never ☐
- 1- Less than monthly ☐
- 2- Monthly ☐
- 3- Weekly ☐
- 4- Daily or almost daily ☐

QA9 AUDIT9. Have you or someone else been injured because of your drinking?

- 0- Never ☐
- 2- Yes, but not in the last three months ☐
- 4- Yes, during the last three months ☐

QA10. AUDIT10. Has a relative, friend, doctor or other health worker been concerned about your drinking or suggested that you should cut down?

- 0-Never ☐
- 2- Yes, but not in the last three months ☐
- 4- Yes, during the last three months ☐

Appendix 7: Session evaluation form completed for each patient by therapists during the case series

Session tape ID:

Date:

Session Evaluation

The questions at end of each session are:

- 1. What is the goal of the overall session? How clearly were you able to define it? To what extent was the goal achieved and why?**

- 2. How was the session delivered (face to face; phone)? If on the phone, why and in what way did this interfere with the session?**

- 3. How long did the session last? How was it broadly structured by goal and define the time taken for each stage.**

- 4. What were the strategies used in order to deliver the required treatment? To what extent were these based on the manual? How did they need to be modified and why?**

- 5. What were the challenges that arose during the session? How were these handled? Was the information provided in the**

manual sufficient to address these challenges or were other sources/information

- 6. What was your overall opinion of the ease with which you carried out this session? Explain answer.**

Appendix 8: Multiple Choice Questions (MCQs) to test post-training knowledge of lay counsellors

Counselling for Alcohol Problems (CAP)

Total number of question stems: 10

Total number of items: 50

Marks: 50

Time: 30 minutes.

Instructions: Each multiple choice question stem is followed by five statements. You must identify which of these statements are True and which are False. One mark will be given for each correct identification (either True or False) while one mark will be deducted for an incorrect identification or for not attempting an answer.

Nº	QUESTION	TRUE	FALSE
1	Some warning signs of drinking problems are		
a	One can drink a lot without becoming drunk		
b	One only drinks 'hard drinks' like feni, urrack, brandy etc.		
c	One only drinks to get drunk		
d	One needs a drink to start the day		
e	One drinks only at the bar		
2	When a person dependent on drinking suddenly reduces or stops his drinking he can get the following symptoms		
a	Shakiness of hands		
b	Vomiting		
c	Itching of hands and feet		
d	Fits		

Nº	QUESTION	TRUE	FALSE
e	Fever		
3	Some self help strategies to reduce drinking include		
a	Drinking foreign made 'good quality' liquor instead of country liquor like feni & urrack		
b	Drinking only with friends		
c	Drinking only at night		
d	Pacing your drinking (e.g. drink more slowly, alternate alcoholic and non-alcoholic drinks, etc.)		
e	Eating before and during drinking		
4	With regards to the structure of PACT-HD		
a	CAP has up to 4 phases and 3 sessions		
b	All three phases can sometimes be done in Session 1		
c	If a patient has never thought about changing his drinking behaviour we should first work together with him to develop a change plan		
d	Agenda for all the sessions should be set at the start of Session 1		
e	We take charge of the counselling process in Session 1 and in subsequent sessions we work together with the patient		
5	These following questions can be used to elicit change talk		
a	What makes you think that you need to make a change in your drinking?		
b	Why don't you listen to your wife when she tells you to stop		

Nº	QUESTION	TRUE	FALSE
	drinking?		
c	If we had the ability to go in the past and correct certain things about your drinking what are those things that you would like to change?		
d	What are your worries about drinking?		
e	Why do you keep drinking when your doctor has told you that your liver is damaged?		
6	The AUDIT will give you information about all areas of the patient's alcohol use, except		
a	How frequently the patient drinks alcohol		
b	How frequently the patient drinks heavily		
c	The age at which the patient first started drinking		
d	Whether the patient has ever stopped drinking		
e	Whether the patient or someone else has been injured because of the former's drinking		
7	When we give Personalised Feedback, we provide the following to the patient		
a	Strategies to reduce or stop his drinking		
b	Give the AUDIT score, explain what it means and how it compares to other men from Goa		
c	Summarise the extent and patterns of the patient's drinking		
d	Summarise the various problems due to drinking that the patient has reported,		
e	Referral to the doctor for treatment of alcohol withdrawal		

Nº	QUESTION	TRUE	FALSE
8	For a patient with drinking problems, controlled drinking (i.e. reducing drinks rather than stopping altogether) might not be a reasonable goal if		
a	He has physical health problems like diabetes or high blood pressure		
b	He has tried to control his drinking in the past and has failed		
c	He is unmarried		
d	He has been drinking heavily for a long time		
e	He drinks stronger alcohol like Feni or Brandy		
9	The Change Plan Worksheet summarises		
a	The changes that the counsellor wants the patient to make		
b	The reasons why the patient wants to make the change		
c	The steps that the patient will take to make the change		
d	When and how to contact the Counsellor when the plan does not work		
e	Possible barriers to implementing the plan		
10	Some strategies to handle urges to drink include the following except		
a	Testing the patient's willpower by going to the bar and not drinking		
b	Getting involved in non drinking activities like cooking a meal		
c	Rather than resisting it or acting on it, sometimes it is useful just allow it to reduce on its own		
d	Drink a soft drink instead of alcohol		
e	Reminding oneself that the urge will reduce on it's own after some time		

Appendix 9: Role-plays for competency evaluation of lay counsellors

Vignette

Dilip is a 45-year-old married bank clerk who has come to the PHC with pain in the abdomen and excessive vomiting since yesterday. He has screened positive for harmful drinking and his doctor has advised him to meet the counsellor.

His drinking has caused problems at the workplace. His manager has warned him that if he comes to work with a hangover he will lose his job. He gets into arguments with his wife, as he does not give her enough money for household expenses. More recently he has been having disturbed sleep and has lost weight. He is not sure why he has to see a counsellor and believes that he does not have any problems related to alcohol. He blames his manager and wife for the problems that he has.

Task for counsellor

Initiate patient engagement as you would if this was the first session with the patient.

Instructions to the actor

You have been drinking alcohol for the past 20 years. You used to drink a couple of bottles of beer with friends over the weekend. Over the past 2 years you have been drinking a quarter of brandy 3 or 4 days a week. You have started having developing health problems recently for which you have come to meet the doctor. You also have problems at work and home. However you blame your wife (arguments) and boss (workplace stress) for all your problems. You don't think alcohol is the cause of your problems and think that your drinking is under control. When the counsellor asks about your drinking, divert his/her attention to how your wife or boss causes problems for you. Towards the end get irritated when the counsellor continues to ask about alcohol problems.

Appendix 10: Quality of CAP (Q-CAP)

Counsellor's Name:	Rater's Name:	Patient ID:
Date of Session:	Date of Rating:	Session #: Phase #:
<input type="checkbox"/> Self Rating (1) <input type="checkbox"/> Peer Rating (2) <input type="checkbox"/> Supervisor Rating (3) <input type="checkbox"/> Peer Rating (4)		
<input type="checkbox"/> Audiotape (1) <input type="checkbox"/> Live (2)		
<input type="checkbox"/> Group Session (1) <input type="checkbox"/> Individual Session (2)		

Scoring Legend

0 = Not done at all; skill not performed

1 = Poor; inappropriate performance with major problems evident; skill delivery is not useful in session

2 = Adequate; skill performed adequately with some problems and/or inconsistencies

3 = Good; Skill performed appropriately; minimal problems and/or inconsistencies; well-timed

4 = Excellent; Skill is highly developed; helpful to patient even in the face of patient difficulties; well-timed and consistently well-performed

Treatment Specific Skills (ALL SESSIONS)

Item	Description		Rating (Circle as appropriate)					
1. Evokes and encourages change talk		Elicits discussion of change (self-motivational statements of change) through questions/comments deigned to promote ↑ awareness/concern for the problem, increase intent/optimism to change, or encourage elaboration on a topic related to change	0	1	2	3	4	N/A
2. Independence		Seeks to enhance patient's sense of control and freedom of choice	0	1	2	3	4	N/A
3. Navigation		Manages the conversation that discussion of the drinking behaviour change remains the focus without causing resistant behaviour	0	1	2	3	4	N/A
4. Information and advice		Gives accurate and relevant information or advice with skilfulness	0	1	2	3	4	N/A
5. Affirmation		Verbally reinforces client's strengths, abilities or efforts to change his/her behaviour?	0	1	2	3	4	N/A
6. Roll with		Provide low-key feedback, roll with resistance (e.g.,	0	1	2	3	4	N/A

resistance	avoiding arguments, shifting focus) and use of a supportive, warm, non-judgemental approach						
7. Discourages sustain talk and encourages discrepancies	Creates or heightens the internal conflicts of the client relative to his/her substance abuse	0	1	2	3	4	N/A
8. Agenda setting	Creates a plan with the patient at the beginning of the session that includes a list of topics to discuss or tasks to complete in the session.	0	1	2	3	4	N/A
9. Involves SO	Involves or enquires about involving significant other in treatment	0	1	2	3	4	N/A
10. Set/Review Homework	Planned/reminded about Action Plan and any specific homework	0	1	2	3	4	N/A
11. Deals with other barriers arising in session	Deals with other challenges that arise in the session (e.g., patient comes in drunk, wants medication, expecting directive advice)	0	1	2	3	4	N/A
Total Score =		Mean Score (number/11-NA) =					

--

<u>BEGINNING</u> Phase Only							
Item	Description		Rating (Circle as appropriate)				
12. Introduces CAP	Explains the number, duration and frequency of sessions. Explains in brief about the content of the sessions: Assessment, feedback, deciding on treatment goals, helping the patient achieve drinking goals and helping the patient to maintain any changes that he makes to his drinking.	0	1	2	3	4	N/A
13. Provides psycho-education and personalised feedback	Helps patient to better understand drinking based on AUDIT assessment; summarizes patient drinking; gives patient personalised feedback	0	1	2	3	4	N/A
14. Goal setting and Action Plan	Helps to set drinking and other-related goals; helps to set change plan and action plan	0	1	2	3	4	N/A
15. Commitment	Asks for commitment from patient about agreed-upon	0	1	2	3	4	N/A

goals

Total Score: _____

Mean Score: Total Number/(4-N/A) = _____

MIDDLE Phase Only

Item	Description	Rating (Circle as appropriate)					
16. Drink refusal Skills	Works with patient to develop skills that the patient can use to say 'NO' when offered or tempted by a drink.	0	1	2	3	4	N/A
17. Handling drinking urges skills	Generates strategies to handle drinking urges in collaboration with the patient.	0	1	2	3	4	N/A
18. Handling emotions skills	Helps the patient to develop the skills for recognising their emotions accurately, identifying the thoughts behind the emotions, identifying the consequences of the thoughts and finally challenging the negative thoughts and replacing them with positive thoughts	0	1	2	3	4	N/A
19. Problem-solving skills	Helps the patient to learn the skills of identifying problems that are contributing to their drinking problem, generate multiple solutions, apply the most appropriate one and review the solution for its effectiveness	0	1	2	3	4	N/A

Total Score: _____

Mean Score: Total Number/(4-N/A) = _____

ENDING Phase Only

Item	Description		Rating (Circle as appropriate)					
20. Reviewed skills	Reviewed problem-solving skills, drink-refusal skills, handling urges and emotions	0	1	2	3	4		N/A
21. Lapse/Relapse management	Helps patient to identify triggers for lapse, develop strategies to prevent exposure to triggers and cope with triggers differently. If lapse has already occurred then help the patient to prevent it turning into a relapse. If relapse has already occurred then help patient to develop skills to prevent recurrence.	0	1	2	3	4		N/A
22. Reviewed all sessions	Asks patient to summarise all of the information and ideas and skills and techniques covered in all the sessions, and then adding in any extra ones that they have forgotten	0	1	2	3	4		N/A
Total Score: _____		Mean Score: Total Number/(3-N/A) = _____						

General Skills (ALL SESSIONS)

Item	Description	Rating (Circle as appropriate)
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23. Non-judgmental	Does not judge and is matter-of-fact in communication with patient.	0	1	2	3	4	N/A
24. Encouraging	Encourages the patient's progress even in fact of obstacles	0	1	2	3	4	N/A
25. Expresses warmth	Displays warmth and care during the session and appears natural and genuine in interactions with patient	0	1	2	3	4	N/A
26. Acknowledges patient's experience	Shows that he/she understood patient's experience	0	1	2	3	4	N/A
27. Empathy	Attempts to demonstrate accurate understanding; normalizes patient's experiences	0	1	2	3	4	N/A
28. Collaboration	Conveys words/actions that therapy is collaborative (vs. counsellor being in charge) where patient is an active participant	0	1	2	3	4	N/A
29. Summarize	Reinforces what has been said, shows that he/she has been listening carefully and prepares patient to move on	0	1	2	3	4	N/A
30. Open-ended	Appropriate use of open-ended questions (beyond	0	1	2	3	4	N/A

questions	yes/no responses)						
31. Active listening	Demonstrates effective listening through non- verbal behaviour (e.g. maintaining eye contact) and verbal behaviour (e.g. reflection)	0	1	2	3	4	N/A
32. Reflection	Selectively reflects content and feelings which promote change talk and reduce sustain talk	0	1	2	3	4	N/A
Total Score: _____		Mean Score: Total Number/(10-N/A) = _____					

Total Mean Score: _____ + _____ + _____ = _____

(Mean Treatment-specific) (Mean Treatment Phase-Specific) (Mean General) (Total Score/3)

Item	Rating				
How difficult was the patient to work with?	0 Not Difficult	1	2 Moderately Difficult	3	4 Extremely Difficult
How would you rate the quality of the audiotape?	0 Poor	1	2 Adequate	3	4 Excellent
Overall, how would you rate the counsellor?	0 Poor	1	2 Adequate	3	4 Excellent

Appendix 11: Timeline Follow Back (TLFB) (Only two months shown for illustrative purposes)

PREMIUM

TIMELINE FOLLOW BACK (TLFB)

Participant ID:

Introduction: *I would like to know from you regarding your alcohol consumption in the past two weeks. For recording this information we will use this calendar. Please try to remember and tell me as accurately as possible.*

January 2014						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1 <u>New Year's Day</u>	2	3	4
5	6	7	8	9	10	11

12	13	14 Makar Sankranti / Pongal	15	16	17	18
19	20	21	22	23	24	25
26 <u>Republic Day</u>	27	28	29	30	31	

February 2014						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1

2	3	4	5	6	7	8
9	10	11	12	13	14 Valentine's Day	15
16	17	18	19	20	21	22
23	24	25	26	27 <u>Maha</u> <u>Shivaratri</u>	28	

Appendix 12: Short Inventory of Problems (SIP-2R)

PREMIUM

Short Inventory of Problems (SIP-2R)

Participant ID:

Instructions: *I will tell you a few incidents that people experience. Please listen to each incident carefully and tell me number of times it had happened with you in last 3 MONTHS.*

Sr. no	During the past 3 MONTHS, about how often has this happened to you?	Never	Once	Once or twice a week	More than twice in a week
1.	I have been unhappy because of my drinking.				
2.	Because of my drinking, I have not eaten properly.				
3.	I have failed to do what is expected of me because of my drinking.				
4.	I have felt guilty or ashamed because of my drinking.				
5.	I have taken foolish risks when I have been drinking.				

Sr. no	During the past 3 MONTHS, about how often has this happened to you?	Never	Once	Once or twice a week	More than twice in a week
6.	When drinking, I have done impulsive things that I regretted later.				

	Now answer these questions about things that may have happened to you. During the Past 3 MONTHS, how much has this happened?	Not at all	A Little	Somewhat	Very Much
7.	My physical health has been harmed by my drinking.				
8.	I have had money problems because of my drinking.				
9.	My physical appearance has been harmed by my drinking.				
10.	My family has been hurt by my drinking.				
11.	A friendship or close relationship has been damaged by my drinking.				
12.	My drinking has gotten in the way of my growth as a person.				
13.	My drinking has damaged my social life, popularity, or reputation.				

	Now answer these questions about things that may have happened to you. During the Past 3 MONTHS, how much has this happened?	Not at all	A Little	Somewhat	Very Much
14.	I have spent too much or lost a lot of money because of my drinking				

	Has this happened to you DURING THE PAST 3 MONTHS?	No	Almost	Yes, once	Yes, more than once
15.	I have had an accident while drinking or intoxicated.				

Appendix 13: PHQ-9 Screening Questionnaire

PREMIUM

PHQ-9 Screening Questionnaire (PHQ-9)

Participant ID:

Introduction: *Now I would like to ask you few questions regarding your health status in last 2 weeks. Each question will have 4 options. Please tell us which of these options is most applicable to you.*

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Trouble falling or staying asleep, or sleeping too much				
2. Feeling tired or having little energy				
3. Poor appetite or overeating				
4. Trouble concentrating on things, such as reading the newspaper or watching the television				
5. Little interest or pleasure in doing things				
6. Feeling down, depressed or hopeless				
7. Feeling bad about yourself- or that you are a failure or have let yourself or your family down				
8. Moving or speaking so slowly that other people could have noticed? Or the opposite- being so fidgety or restless that you have been moving around a lot more than usual				

9. Thoughts that you would be better off dead, or of hurting yourself in some way.					
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?					
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult		

Please proceed to ask this question on suicide attempt.

11. IN THE PAST 3 MONTHS have you made an attempt to take your life, by taking an overdose of tablets or insecticide or in some other way?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

Event date.....

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Appendix 14: Session evaluation for case series with lay counsellors

SESSION EVALUATION

Participant ID:

Date of session:

1. What was the goal of the session?

2. How was the session delivered (Tick)?

☐ Face to face

☐ Telephone

☐ Home Visit

2a. Reasons for conducting phone session or home visit

2b. If on the phone, did it interfere with the session?

3. Duration Of Session (in minutes):

4. What were the strategies used in order to deliver the required treatment?

Strategies/ Used	Techniques	Tick if done	Comments
Assessment built on AUDIT scores			
Personalised feedback			
Developing motivation			
Relapse prevention			

Problem solving		
Drink refusal skills		
Handling emotions effectively		
Handling drinking urges		
Change plan worksheet		
Additional strategies/techniques used with reasons for their use:		

5. Was the significant other (SO) present for the session?

- ☐ Yes
- ☐ No

6. In which part of the treatment was the SO involved?

- ☐ Assessment
- ☐ Change plan
- ☐ Both

7. Please describe the experience of involving SO in the assessment?

8. What were the difficulties faced during the session? How were these handled?

Appendix 15: End of treatment evaluation form for case series with lay counsellors.

END OF CAP TREATMENT PATIENT EVALUATION FORM

Participant ID: _____ **Date of discharge:** _____

1. Reason for discharge (Tick ONLY ONE response)

- 1.1 Planned discharge ☐
- 1.2 Drop out (i.e. 3 missed appointments) ☐
- 1.3 Change in place of residence ☐
- 1.4 Death of patient ☐
- 1.5 Referral out of the program (specify) ☐
- 1.6 Refusal to continue ☐
- 1.7 Other (Please specify) ☐

2. What was the overall response of the patient to the treatment? (Tick ONLY ONE response)

- 2.1 Recovered ☐
- 2.2 Partly improved ☐
- 2.3 No change ☐
- 2.4 Worsened ☐
- 2.5 Explain your rating in the box below

3. What strategies were the most helpful? (Tick all that apply)

- 3.1 Personalised feedback ☐
- 3.2 Problem solving ☐
- 3.3 Drink refusal skills ☐
- 3.4 Handling emotions ☐
- 3.5 Handling drinking urges ☐

- 3.6 Developing motivation for change ☐
- 3.7 Involving the SO ☐
- 3.8 Any other (Please give details below) ☐

3.9 Explain why these were the most useful strategies

4. What were the barriers to successfully delivering the treatment?

(Tick all that apply)

4.1 Patient did not respond to the treatment

☐

4.2 Patient did not follow through on the treatment expectations, e.g.
homework ☐

4.3 Patient did not have time

☐

4.4 Patient was not cooperative

☐

4.5 Family was not cooperative

☐

4.6 Patient could not understand a concept or strategy

☐

4.7 Patient had a physical illness

☐

4.8 Counsellor related issues (Please specify)

☐

4.9 Any other (Please specify)

4.10 Please elaborate your response below

Appendix 16: Question guide for IDI with patients who participated in the case series with lay counsellors.

Objectives

1. To understand patients' (patients who have completed the treatment and patients who dropped out) experiences of the CAP treatment;
2. To explore patients' understanding of the CAP treatment;
3. To understand patients' acceptance of the CAP treatment and lay counsellors; and
4. To understand challenges and difficulties faced by the patients in completing the treatment and the ways to overcome these challenges

Guiding questions

1. *You had visited the PHC around XXX (month). Could you tell me more about the reason you went there for?*

Probe: Illness for which you sought the treatment?

2. *How has your health been since then? What changes have occurred since then? Why have these changes occurred/not occurred (as appropriate)?*
3. *When you visited the PHC, you met a couple of new people viz. a health assistant and health counsellor. I would like to ask you few questions regarding your interaction with the counsellor.*

After asking you to respond to a couple of questionnaires, the health assistant escorted you to the health counsellor. The counsellor provided you counselling services on xx (number of occasions). Can you tell me about your interaction with him/her? What did you like? What did you dislike?

Probe:

- *What was your impression about the purpose of the counselling? What did you expect from the counselling treatment? Did the counselling offered by the counsellor meet your needs/expectations? If yes, how? If no, why not?*

- *What information/advice did you receive from the counsellor? How useful that information/advice was for you? Why?*
- *What did you find most beneficial about the interaction/sessions? Why?*
- *What did you find the least beneficial about the interaction/sessions? Why?*
- *What do you think about the way the counsellor tried to help you? What would you suggest to the counsellor for improvement?*
- *What is your opinion about counsellor's knowledge, skills and capacities to handle your problems or such kinds of problems of other patients?*

4. Now I will ask you about the xx (number of sessions) sessions attended by you.

Style of delivery

- *Instead of giving you some direct advice, the counsellor tried to work with you on your health problems. What do you think of this?*
- *What kind of challenges did you experience during the sessions? How did you overcome these challenges? What did the counsellor do to help you overcome these challenges? What can be done by the counsellor to overcome these challenges?*

Concept:

- *Every time you visited the counsellor, she/he asked you some questions, asked you about your problem/s, tried to find out solutions to those problems and gave you some home work. Did you understand the purpose of "treatment by talking"?*
- *Did you understand the purpose of the activities that you were asked to do at the clinic or at home?*
- *How did the counsellor help you to understand the concept of counselling/treatment by talking?*

Frequency:

- *The counsellor asked you to visit the PHC after every week or 15 days for follow-up sessions, what do you think of it?*
- *What barriers did you face in attending these follow-up sessions? How did you try to solve these problems? In your opinion, what could the counsellor do in this regard?*

Duration:

- *Every session that you attended was of 45 minutes to one hour. What do you think of the duration of these sessions? Do you have any suggestions regarding the length of these sessions?*

Delivery method:

You attended few sessions in the PHC. How was your experience of availing counselling sessions at the PHC?

What kinds of challenges did you face during the sessions offered in PHC? What could the counsellor have done to help you in addressing these challenges?

You were also given a choice of availing the counselling services at your home.

[If the participant has availed the home-based counselling]

How was your experience of receiving counselling session at home? What kinds of challenges did you experience during the home visit? What can be done to solve these challenges?

[If the participant has not availed the home-based counselling]

What do you think of receiving counselling sessions at home? What kind of challenges do you foresee in it? What kinds of suggestions do you have to improve the home-based counselling?

You were also given a choice of availing counselling sessions over telephone, what do you think of it?

[If the participant has availed telephonic counselling session] how was your experience of receiving session over telephone?

What kinds of challenges did you experience in it?

What kinds of suggestions do you have to improve the telephone-based counselling?

5. *During your visits to the PHC, the health counsellor shared with you some reading material. How did you like that material?*

Probe:

- *How useful was this material for you?*
- *What challenges did you face in reading and understanding the material provided to you?*
- *What is your opinion about the language used in those hand-outs?*
- *Was it easy or difficult to understand the pictures given in that material?*
- *What changes would you suggest to make it easier for patients like you?*

6. **[Only to the patients who have completed the treatment]**

- *What things/factors helped you in completing the treatment?*
- *Who helped/motivated you in completing the treatment?*

7. **[Only to the patients who have completed the treatment]**

- *What did you learn from these sessions?*
- *How confident are you about using the techniques and skills that you have learnt during this treatment if similar kinds of problems come up again in your life?*

8. **[Only to the dropped out patients]**

- *You did not return to see the counsellor after your (XXX) meeting with her/him. Could you share the reasons for not coming back?*
- *What could the counsellor or PHC have done to make it possible for you to continue the counselling?*

9. **[Only to the dropped out patients]**

- *Is there anything else that could be done that you think would make a difference in helping you recover from your health problems?*

Appendix 17: Question guide for FGD with lay counsellors who delivered CAP in the case series

Objectives:

- To understand the experiences of counsellors of delivering CAP in the PHC setting; identify barriers and test strategies to address them;
- To assess the feasibility of providing counselling treatment using various delivery methods tailored to patient preferences (for e.g. clinic based, home based, telephone based) and describe strategies to overcome the barriers to delivery; and
- To assess the procedures employed for counsellors to acquire and maintain competency, including group supervision.

Guiding questions:

1. *To begin with, could you please tell us something about your overall work experience in the PHC over the last one month?*
2. *What was your experience of incorporating your role within the already existing PHC routine? What factors helped or made the process easy? What were the challenges? How were these challenges addressed? What more could have been done to tackle these challenges?*
3. *Now let us discuss about your experience of providing counselling. How was your experience of providing counselling? What was your experience in being accepted by patients? What factors made the process easy? Were there any difficulties?*
4. *How was your experience of providing counselling services to patients? What kinds of difficulties did you face? How did you address these difficulties?*

5. *How was your experience with patient follow-up? What kind of challenges do you face in contacting patients for the follow-up sessions? What can be done to address these challenges?*
6. *What do you think about the overall response of the SOs to the program so far? Can you share a successful experience of SO involvement? What kind of challenges do you face in involving SOs in the program? What can be done to address these challenges?*
7. *Now let us discuss about the delivery method/mode of the counselling treatment for both the disorders.*
 - *How was your experience of delivering face-to-face counselling for last one month?*
 - *What kinds of challenges or barriers did you face during face-to-face counselling? What can be done to address these barriers? (Note: Please ask for each barrier/difficulty)*
 - *How was your experience of delivering counselling over telephone for last one month?*
 - *What kind of challenges or barriers did you face in providing counselling over telephone? What can be done to address these barriers? (Note: Please ask for each barrier/difficulty)*
8. *Now we will discuss about the location of providing counselling services i.e. at the PHC or at home.*
 - *How was your experience of delivering counselling at the PHC for last one month?*
 - *What kinds of challenges or barriers did you face in providing counselling at PHC? What can be done to address these barriers? (Note: Please ask for each barrier/difficulty)*
 - *How was your experience of delivering counselling at patient's home?*
 - *What kinds of challenges or barriers did you face in providing counselling over telephone? What can be done to address these barriers? (Note: Please ask for each barrier/difficulty)*

10. *How was your experience with various hand-outs developed for patients?*

- *What do you think about their usefulness?*
- *What would you suggest to improve the usage of hand-outs for patients?*
- *Any issues with translation or pictorial representation in the hand-outs?*
- *What kinds of challenges or barriers did you face in using the hand-outs? What can be done to address these barriers?*

4. *Now we will discuss about your supervision. First we will discuss about the one to one supervision.*

What do you think of one to one supervision? What do you find useful in one to one supervision? What is not so useful in one to one supervision?

Probe on:

- i. *Frequency of one to one supervision*
- ii. *Duration of one to one supervision*
- iii. *Quality of one to one supervision*
- iv. *What kind of learning happens during this supervision?*
- v. *What kind of challenges and difficulties do you face during this supervision?*
- vi. *What can be done to address these barriers? How can this supervision method be improved? (Note: Please ask for each barrier/difficulty)*

What do you think of peer-group supervision? What do you find useful in peer-group supervision? What is not so useful in peer-group supervision?

Probe on:

- i. *Frequency of peer-group supervision*
- ii. *Duration of peer-group supervision*

- iii. Quality of the peer-group supervision
- iv. Fairness in peer-group supervision
- v. *What kind of learning happens during this supervision?*
- vi. *What kind of challenges and difficulties do you face during this supervision?*
- vii. *What can be done to address these barriers? How can this supervision method be improved?* (Note: Please ask for each barrier/difficulty)

Appendix 18: Question guide for IDI with counsellor supervisors

Objectives:

- To understand challenges and difficulties experienced by the intervention team in delivering psychosocial treatment at PHC and at home, and the ways to address these challenges; and
- To understand the challenges faced during supervision of the counsellors and the ways to overcome these challenges.

Guiding questions:

1. *Let us first talk about the counselling services.*

What are your observations on providing counselling at the PHC to harmful drinkers? Any differences between harmful drinkers and dependent drinkers? What were/are these challenges and difficulties in providing counselling at the PHC to harmful drinkers? How were these challenges addressed?

2. *What are your observations on providing counselling at the home of the harmful drinkers? Any differences between harmful drinkers and dependent drinkers? What were/are the challenges and difficulties in delivering CAP at patients' homes? How were these challenges addressed?*

3. *Now, we will talk about the patient follow-up. How was the experience of the counsellors with patient follow-up?*

Probe on:

- Any differences among the responses from harmful drinkers and dependent drinkers?
4. *What kinds of challenges are faced by the counsellors in ensuring patient follow-up? What is done to tackle these challenges or difficulties? What more can be done to address these challenges?*

5. *What do you think about the overall response of the SOs to the program so far? What kind of challenges do you face in involving SOs in the program? What can be done to address these challenges?*
6. *Now, we will discuss about the supervision process. What do you think about the overall competencies of the counsellor in providing the manualised treatment to the harmful drinkers? What kinds of challenges are faced by the counsellors in maintaining the treatment fidelity? What is done to address these challenges? What can be done to address these challenges?*
7. *Now, we will discuss about the group supervision process. How is your overall experience of the group supervision?*

Probe on:

- Frequency of peer-group supervision?
- Duration of peer-group supervision?
- Quality of the peer-group supervision?
- *What kind of challenges and difficulties do you face during this supervision?*
- *What can be done to address these barriers? How can this supervision method be improved? (Note: Please ask for each barrier/difficulty)*

8. *How is your overall experience of one to one supervision?*

Probe on:

- i. Frequency of one to one supervision?
- ii. Duration of one to one supervision?
- iii. Quality of the one to one supervision?
- iv. *What kind of challenges and difficulties do you face during this supervision?*
- v. *What can be done to address these barriers? How can this supervision method be improved? (Note: Please ask for each barrier/difficulty)*

Appendix 19: Question guide for IDI with SOs of patients who participated in the case series

Objectives:

- To understand SO's involvement in the psychosocial treatment of the patient;
- To explore SO's expectations from the treatment;
- To understand perceived impact of the treatment on the patient and family;
- To understand challenges and barriers experienced by the patient and the family in completing the treatment and ways to address them; and
- To understand opinions on material provided by the counsellor.

Guiding questions:

9. *You have visited the PHC around XXX (month) with your (relationship with the patient). Could you tell me more about the reason you went for?*

Probe:

- Illness for which patient sought the treatment

10. *How has the health of the patient been since then? What changes have occurred since then? Why have these changes occurred/not occurred (as appropriate)?*

11. *We will now talk about your involvement in the treatment of your (relationship with the patient). When you visited the PHC, you were briefed about your (relationship with the patient) health problem by the counsellor and you are involved in the treatment since then. How was your experience of being involved in the treatment?*

Probe:

- *What were you explained about the health problem of your (relationship with the patient)?*
- *What were you explained about the treatment? What challenges or difficulties did you face in understanding the information given by the health counsellor? What could have been done to explain you the information in better way?*
- *What did you find most beneficial about your involvement in the sessions? Why?*
- *What did you find the least beneficial about your involvement in the sessions? Why?*
- *What do you think about the way counsellor involved you in the treatment? What could have been done to increase your involvement in the treatment?*
- *What did you expect from the treatment? Did the treatment meet your expectations? If yes, how? If no, why not?*
- *What is your opinion about counsellor's knowledge, skills and capacities to handle your (relationship with the patient) problems?*

12. Now we will talk about the impact of the treatment? What changes have you observed in the patient since the treatment has begun? What changes have you observed in the family since the treatment has begun?

Probe:

- *In your opinion, what changes have occurred due to the treatment by the counsellor?*

13. You might be aware that the patient was given an option to avail the services of counsellors either at the PHC, at home or over telephone. We will talk about your experiences of your involvement during these various options.

First we will talk about the PHC based counselling. How was your experience of coming for the treatment with the patient at PHC? What kinds of challenges or difficulties did you face? What did you do to overcome these barriers? What can be done by the counsellor to help you in overcoming these barriers?

The patient was also given an option of availing the counselling sessions at your home.

[If the patient has received counselling sessions at home]

What was your experience of providing counselling sessions to the patient at home? What kind of challenges or difficulties did you experience? What did you do to overcome these barriers? What can be done by the counsellor to help you in overcoming these barriers?

[If the patient has not received counselling sessions at home]

What kind of challenges or difficulties do you see in the counsellor visiting your home for sessions? What can be done by the counsellor to help you in overcoming these barriers?

The patient was also given an option of availing the counselling sessions over telephone.

[If the patient has received counselling sessions over telephone]

What did you think of the patient receiving the counselling sessions over phone? What kind of challenges or difficulties did you experience? What did you do to overcome these barriers? What can be done by the counsellor to help you in overcoming these barriers?

[If the patient has not received counselling sessions at home]

What kind of challenges or difficulties do you see in receiving sessions over telephone? What can be done by the counsellor to help you in overcoming these barriers?

14. *During your visits with the counsellor, s/he shared with you some reading material. How did you like that material?*

Probe:

- *How useful was this material for you?*
- *What challenges did you face in reading and understanding the material provided to you?*
- *What is your opinion about the language used in those hand-outs?*
- *How easy or difficult was it to understand the pictures given in that material?*
- *What changes would you suggest to make it easier for relatives of the patients like you?*

Appendix 20: Instructions to actor in the standardised role-play to test competency of lay counsellors at the end of the case series

Actor Script for PHASE 1, Scenario 1A, CHARACTER 1: Nikhil Chamundar

You are playing the role of Nikhil Chamundar in the scenario below:

Nikhil Chamundar is a 29-year-old married man with 2 children. He recently had a bike accident when riding under the influence of alcohol, on his way back from the nearest bar, and broke his hand, which has been in plaster since then. He used to work as a driver, but couldn't continue working after his accident, and therefore lost his job. He has come to the PHC alone, to get the plaster cast removed.

The accident made him realise how alcohol is ruining his life. This has been a trigger for changing his drinking habits as he has begun to realise that his drinking has created big problems in his life. He is very eager to know what he should do to change. He is very cooperative with the counsellor, but seems to be in a rush to know how he can change his drinking problem.

Please provide the following information, as appropriate during the role-play:

1. **The counsellor might begin as follows:** *"So Mr Chamundar, we have set the agenda for the session and agreed that our first task today is to get a better understanding of your drinking"*

PLEASE INTERRUPT THE COUNSELLOR AT THIS STAGE, SAYING:

"Yes, drinking is completely destroying/ruining my life. I have decided to give up drinking completely; how can you help me with this?"

2. **The counsellor should ask you the following questions. Please respond as detailed below**

COUNSELLOR QUESTION	ACTOR RESPONSE
What do you normally drink?	<i>I mostly drink beer, but on the weekends I have vodka</i>
Where do you normally drink?	<i>At a bar, it's a little distance from my house.</i>
Do you drink by yourself or do you drink with others?	<i>I used to always drink with my friends. But after losing my job, I sometimes drink by myself in the daytime.</i>
Has drinking ever caused you problems of any kind?	<p><i>Yes, I had a bike accident when driving back from the bar after drinking with my friends one weekend.</i></p> <p><i>I was seriously injured, and therefore I could not continue my job as a driver, so they fired me. Since then I have not been able to find work, and have come to get the plaster cast removed from my hand today.</i></p> <p>Response to further questioning:</p> <p><i>I don't feel like doing anything after I drink in the day, I just come home and sleep. My wife gets irritated with me because of this; she says I'm not bothered about finding a new job. My wife has a part time job, but without my income, we are having a difficult time managing the household and paying for the children's expenses.</i></p>

3. The counsellor might ask some of the following questions, in which case you must provide the following information:

- *How often do you drink to the point of getting drunk?*
 - *At least once a week, usually on the weekends when I drink hard liquor with my friends.*
- *At what age did you start drinking?*
 - *I'm not sure. Quite recently, maybe about 3 years ago when I started drinking with my friends.*
- *Have you ever tried to give up drinking? What happened?*
 - *Yes, ever since my accident I've tried to drink less. I've stopped drinking vodka altogether, but I'm finding it quite difficult to stop drinking beer. I find that drinking helps me forget the tension of being unemployed and all my financial worries, at least for a little while.*
- *What is the longest period you've gone without drinking?*
 - *About three to four days I think.*

Appendix 21: Counsellor instructions for the role-play

Counsellor Instructions – Scenario 1A, PHASE 1

You have five minutes to prepare for the role-play. In this time you may refer to as much of the written background information on the patient as you wish – you don't need to read it all. You are treating Nikhil Chamundar, who has been identified as a harmful drinker. The actor will inform you when five minutes have passed, and then you will **have up to 10 minutes to role-play being Nikhil's counsellor**, as per the instructions outlined below.

Background information about Nikhil Chamundar

Nikhil Chamundar is a 29-year-old married man with 2 children. He started drinking about 3 years ago. He recently had a bike accident when driving under the influence of alcohol, on his way back from the nearest bar, and broke his hand, which has been in plaster since then. He used to work as a driver for a company, but couldn't continue working after his accident, and therefore lost his job. He came to the PHC to get his cast removed, on the day he was screened using the AUDIT.

Context of the current session

- You are in session 1 with Nikhil. You will begin treating Nikhil with the harmful-drinking intervention according to the treatment manual, at the PHC.
- One week ago, he was assessed by a Health Assistant at the PHC and completed the AUDIT.
- You have already set the agenda and agreed to open the main part of the session by getting to know more about the patient's drinking, based on his AUDIT responses which you have with you.

Remember that this role-play is simply designed to capture a short sample of treatment so just do what seems reasonable in the 10 minutes you have available. You will be timed and the ringing of the timer will signal that the role-play is over.

INSTRUCTIONS for the session:

You have already collaboratively established the agenda for the session, which is to get a better understanding of the patient's drinking problem based on the AUDIT assessment. PLEASE SEE ATTACHED 'AUDIT'.

You can begin with a statement like, "*So Mr Chamundar, we have set the agenda for the session and agreed that our first task today is to get a better understanding of your drinking*"

Appendix 22: Rating sheet for role-play

PHASE 1, SCENARIO 1 - PROCEDURE CHECKLIST

Counsellor task: To better understand the patient's drinking and provide personalised feedback

Core Features – These features should all be present	
<ol style="list-style-type: none"> 1. The counsellor should review the patient's AUDIT responses, and confirm that the patient is still happy with responses (scoring 2 or more) which indicate a potential problem with alcohol 2. The counsellor should gain a thorough understanding of the patient's drinking problem by asking the patient detailed follow-up questions. The following questions <u>MUST</u> be asked as part of the assessment: <ol style="list-style-type: none"> a. What do you normally drink? b. Where do you normally drink? c. Do you drink by yourself or do you drink with others? 3. The counsellor should make further enquiries about the kind of problems the patient reported on the AUDIT/other problems caused by his drinking (e.g. - You said on this questionnaire that you (State the problems recorded on the AUDIT)...Can you tell me a bit more about this? Have you had problems in any other areas?) 4. The counsellor should avoid doing things that would be inconsistent with or interfere with the procedure. In this case the counsellor <u>should not</u>: <ol style="list-style-type: none"> a. Begin by telling him the results of the AUDIT screening (score) but should instead ask the patient's permission to discuss the AUDIT responses b. Carry out the assessment as if completing a check-list (rather, counsellor should use reflection, and obtain 	

<p>useful information by probing for details)</p> <p>5. After assessing the drinking problem, the counsellor should provide the patient with personalised feedback about the problem, by doing the following:</p> <ol style="list-style-type: none"> Explain that he/she would like to feed-back to the patient their interpretation of the information that he has provided Provide the patient with his AUDIT score and explain what the AUDIT score means, (i.e. – a <i>‘Harmful drinker’ is someone who drinks at a level which is causing harm to his physical and/or mental health.</i>) Summarise the extent and patterns of the patient’s drinking Summarise the various problems due to drinking that the patient has reported <p>6. After providing personalised feedback, the counsellor should elicit the patient’s opinion response to the summary.</p>	
<p>Conditional Core Features</p> <p>If the is met by the actor, then the counsellor should behave as described in the feature. If the conditional requirement is not met then the item is not applicable, please record N/A</p>	
<p>7. <u>If Nikhil states that he wants to give up drinking completely and asks how the counsellor can help him with this,</u> then the counsellor should:</p> <ol style="list-style-type: none"> Praise/affirm that this is certainly a possible route that the counselling will take, and that if that is what the patient wants, then the counsellor can certainly help him to achieve this Navigate Nikhil back to the discussion about his drinking, indicating that before he and the counsellor decide together what needs to 	

change, it is first important to get a better understanding of his drinking	
Optional Features- The counsellor may or may not fulfil these features.	
<p>8. The counsellor may suggest that the patient maintains a drinking diary and explains how to use it, (i.e. - by filling in the drinking diary sheet with details of what he has been drinking – how much, when, where, and with whom).</p> <p>9. The counsellor may explain the importance of bringing a ‘Significant Other’ (SO) along to the next session, (i.e.- The patient can get to hear more about how his drinking is affecting his SO; there may be things about his drinking that the patient cannot recall that his SO can, the SO may hear learn more about the impact of drinking on the patient’s life and may then be more motivated to help the patient change.)</p>	

Please make the Procedure rating for this scenario on the following scale: (See N.B.)

0	Absence of CAP procedures specified in the scenario-specific guidelines
2	Limited application of CAP procedures / inconsistent application of procedures, i.e. <u>few</u> of the scenario-specific features were present
4	Moderate application of CAP procedures , i.e. <u>most</u> of the scenario-specific features were present
6	Consistent application of CAP procedures , i.e. <u>all</u> of the scenario-specific core features were present

Note: The **final procedure rating** is made on a **scale of 0 – 6**. The procedure rating should be based on a consideration of the presence/absence of the **core and conditional core features** defined in the procedure checklist. If any of the conditional features are marked as NA, the facilitator **should not** be penalised for these items in the final procedure rating.

- *A rating of 1 should be made if it is not quite possible to rate 0*
- *A rating of 3 should be made if it is not possible to decide between a rating of 2 and 4*
- *A rating of 5 should be made if it is not quite possible to make a rating of 6*
- *If despite following these three guidelines, it is impossible to decide between two adjacent ratings, the higher rating should be chosen*

Appendix 23: Perceived global competency and attitude towards work of lay counsellors

PREMIUM: Supervisor's Rating of Counsellor

Instructions:

This form is to be filled by each PREMIUM supervisor independently. Kindly do not discuss the ratings with each other before or after filling this form.

Choose a rating for every counsellor for following two questions and write it in the table provided.

- 1. According to you, how competent (Name of the counsellor) is in delivering the psychological treatment to the patients?**

1	2	3	4	5
Poor	Little bit	Moderate	High	Excellent

- 2. According to you, how committed (Name of the counsellor) is to providing the psychological treatment to the patients?**

1	2	3	4	5
Poor	Little bit	Moderate	High	Excellent

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